

MODULE

6

Legal and human rights

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Outcomes of this module

By the end of this module, you should be able to:

1. Describe what human rights are.
2. Explain different kinds of human rights.
3. Describe what legal rights are.
4. Identify which rights are important to HIV vaccine trial participants and why.
5. Discuss how the draft *SAAVI Preventative HIV Vaccine Trial Participant Charter of Rights* tries to raise awareness about the rights of trial participants.



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



Section 1: Background information on legal and human rights and HIV vaccine research and development

1. WHAT ARE HUMAN RIGHTS?

Take 5 minutes ...

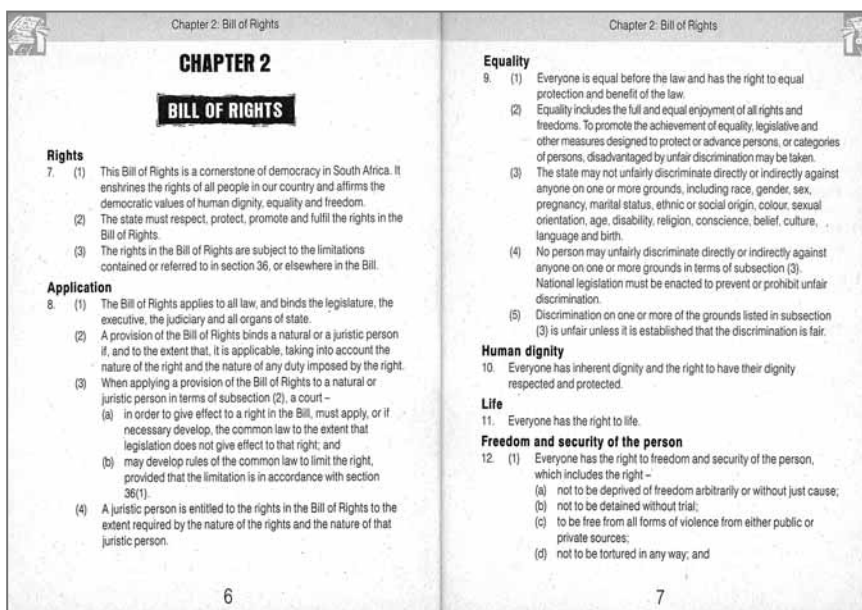
- Can you think of an example of a human right?
- Can you think of an example of how in your experience a human right has been abused?
- How would you define a human right?
- Where do human rights come from?

Human rights are rights and freedoms that everyone has, just because they are human. For example, every person has the right to life. No one can take these rights away from us. But sometimes these rights can be limited because of other rights that exist, or because of other people's rights, or because of what the Constitution of a country says.

KEY WORD

Human rights:

Rights that belong to us because we are human.



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

KEY WORDS

Custom:

Fixed practices in a community.

Aspirational:

Motivational, encouraging.

The idea of human rights can be understood to come from different sources, including from religions, from **custom** and from the law. Human rights can also be seen as having been achieved through struggle and then being written into legal and '**aspirational**' documents. In South Africa, we have now written these rights into our Constitution, in a Bill of Rights. The Constitution is the highest law in South Africa. All other laws and state actions must be in line with the Constitution.



Although our human rights are written in the Constitution, they must still be **interpreted** or given meaning. This happens in different ways – one way is by the courts. When the courts interpret human rights they look at the immediate facts of the case before them, and at the social and historical background or situation. But we generally only take human rights issues to court as a last resort – after trying all other ways of working out the matter. Sometimes we take a human rights issue to court if it has **merit** and will benefit many people or will affect how the courts interpret the law in the future.

Whenever we discuss human rights issues in relation to HIV vaccine research and development, we need to take into account the context or circumstances within which this research and development is taking place. This is especially important when workshop participants discuss any of the case studies in this Module. We need to put these case studies in context and to encourage workshop participants to recognise that much of South African society still suffers from a history of underdevelopment and still experiences a high degree of inequality and unfairness. This is especially true when it comes to issues around gender (e.g. male/female power relations), and to the different health and socio-economic conditions found in different communities. We need to interpret human rights issues against this background of inequality and underdevelopment.

How are our human rights ensured?

The state has a duty to respect, protect, promote and fulfill human rights. Let's look at generally what each of these duties 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. (See page 14 for more information about unfair discrimination.)

Protecting human rights: This is the duty to take action to protect our rights from being **violated** or abused by anyone.

Promoting and fulfilling human rights: The duty to take reasonable **legislative, financial and judicial** steps to make it possible for people to use and enjoy their rights. An important step is to tell people about their rights and how they can enjoy and can use these rights.

Individuals, communities and other institutions also have certain duties to ensure human rights. Later in this module you will have an opportunity to explore ways to ensure human rights in HIV vaccine research and development, including in clinical trials. You will see that there are various bodies that can play a specific role in this, including:

- The Research Ethics Committees (RECs), the Medicines Control Council (MCC) and the Community Advisory Groups (CAGs).

KEY WORDS

Interpreted:

Given meaning.

Merit:

The factual content of a matter.

Violated:

Abused, dishonoured.

Legislative:

Law-making measures to realise human rights.

Financial:

Measures to ensure that enough money is put aside to realise human rights.

Judicial:

Decisions by judges, or persons or bodies fulfilling a similar role to realise human rights.

For more information on human rights, contact the South African Human Rights Commission at www.sahrc.org.za or phone (011) 484 8300.



SAAVI Info-line no.:

080 822 2463
or
080 VAC CINE

Refer to Chapter 9 of the Constitution for a full list of state institutions that strengthen our constitutional democracy.

- The **SAAVI Info-line** can also refer you to more information and assistance on human rights.
- Chapter 9 of the Constitution also lists state institutions that can help to ensure human rights, such as the Human Rights Commission, the Gender Commission and the Public Protector.
- The courts may also play a role – but as we said, this is usually as a last resort – only after we have tried all other ways of working out the matter.

2. WHAT ARE THE DIFFERENT KINDS OF HUMAN RIGHTS?

We can generally group the human rights that are written into the Bill of Rights into:

- civil and political human rights; and
- socio-economic human rights.

Take 5 minutes ...

- *Turn to the South African Bill of Rights in Appendix 1 at the end of this section (page 24). Which human rights do you think are examples of civil and political rights?*
- *How would you define a civil and political right?*
- *Which civil and political rights do you think are relevant to participants in the HIV vaccine trials?*

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

Adapted from the Constitution of the Republic of South Africa, 1996.



In the past, **civil** and political rights were seen as those rights that prevented the state from doing something. Today it is understood that sometimes civil and political rights are rights that require the state to also do something positive to ensure our civil and political rights. For example, the right to vote requires the state to take positive action to ensure that we can exercise our right to vote on voting day.

The following are some examples of civil and political rights that apply to in HIV vaccine research and development:

- The right not to be subjected to medical or scientific experiments without informed consent (Bill of Rights, Section 12 (2) (c)).
- The right to equality (Bill of Rights, Section 9).

What are socio-economic human rights?

Take 5 minutes ...

- *Can you think of an example of a socio-economic right? Look at the Bill of Rights in Appendix 1 on page 24 for ideas.*
- *How would you define a socio-economic right?*
- *Which socio-economic rights do you think are relevant to participants in the HIV vaccine trials?*



Progressive realisation of the socio-economic right to housing.

Socio-economic rights are to do with people's **social, economic** and cultural security. These rights cannot be claimed by individuals, but are rather seen as collective or communal rights, for example, a group of people's right to housing, water, health care, education.

Socio-economic rights say that the state must take positive action to make sure that these rights are increasingly fulfilled over time. This is called **progressive realisation**. For example, the state must make reasonable plans and provide the necessary money so that over time the socio-economic rights of people to health care, housing, education, etc. can be fulfilled.

As we will see further on, an example of a socio-economic right that is relevant to HIV vaccine research and development is the right of **access** to health care services. In the South African courts

KEY WORD

Civil:
Public, social.

KEY WORDS

Social:
To do with people.

Economic:
To do with money and the economy.

Progressive realisation:
To take positive action to make sure that these rights are increasingly fulfilled over time.

Access:
Opportunity to use.



For further information on human rights, read *My rights, your rights* by The South African Human Rights Commission (SAHRC).

For further information on mother-to-child transmission of HIV, see Module 2.

KEY WORD

Applied:
Put to use.

an example of a case involving this right was the TAC (Treatment Action Campaign) versus the SA government. In this case, the court decided that the right to health meant that government must have a reasonable plan to make sure that antiretroviral treatment was available to prevent mother-to-child transmission of HIV.

3. WHAT ARE LEGAL RIGHTS?

Take 5 minutes ...

- *Can you think of an example of a legal right?*
- *How would you define a legal right?*
- *Is a legal right the same thing as a human right? How are they the same and how are they different?*
- *Which legal rights are relevant to the HIV vaccine research?*

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

DID YOU KNOW?

The law is a set of rules which govern the way people behave. These rules tell us what we must do; what we are allowed to do; and what we must not do. So the law tells us what our rights (what we can do) and duties (what we must do) are.

In South Africa we have a democratic system of government. This means that we can all be involved in and contribute to making the law of our country. We can do this by voting in elections for people to represent our views, or by voicing our opinions, e.g. commenting on proposed laws.



Where do our legal rights come from?

In South Africa our legal rights come from:

- the Constitution;
- other statutes;
- common law;
- customary law; and
- court decisions.

The Constitution: You already know that the Constitution is the highest law of South Africa. The Constitution is also a **statute** or written law. All other laws and state actions must be in line with the Constitution. The Constitution tells us how the state must be organised and it includes the Bill of Rights. We can challenge laws, and the Constitutional Court can **strike down** laws that go against the Constitution. When the courts interpret the Bill of Rights, they must also look at international law and even foreign law for

KEY WORDS

Statute:
Written law.

Strike down:
Cancel.



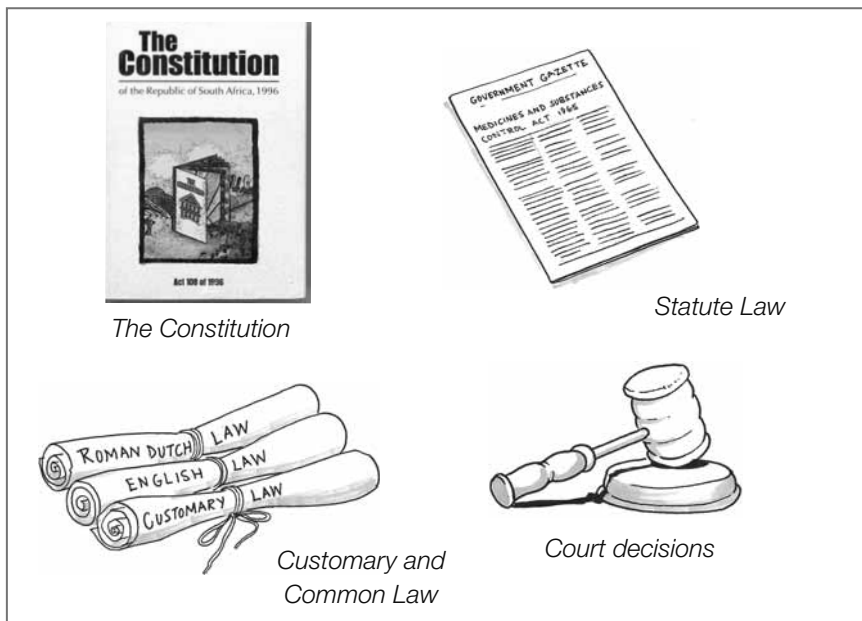
guidance. Our Constitution says that whenever a court, tribunal or forum is involved in interpreting any legislation, for the purposes of developing the common law or customary law, they must promote the spirit, **purport** and objects of the Bill of Rights.

Statute law: These are written laws which are called statutes or Acts. A new statute can change everything the old law said or it can put in place a completely new law, for example, dealing with new technology. Statutes are made by Parliament, which is the highest law-making body in the country. Statutes can also be made by provincial parliaments and even by local governments. A statute can give a person (e.g. a Minister) power to make more laws that complement a statute – called **regulations**.

KEY WORDS

Purport:
Intent or purpose.

Regulations:
Laws that complement a statute. These might only apply to specific areas.



Some examples of statutes that apply to HIV vaccine research and development are the *Medicines and Substances Control Act* of 1965 and the *National Health Act* of 2003. They specify how research such as HIV vaccine research must undergo regulatory and ethical review. The *National Health Act* also deals with aspects of the rights of children involved in research.

Common law: This is law that is not made by Parliament or any other law-making body. This law comes from Roman-Dutch and English law which was brought to South Africa long ago by Dutch and English settlers. When a legal problem is not covered by Statute Law, then we can look to the Common Law for relevant legal principles. Many of the general principles of our law come from Common Law, e.g. the initial general principles about informed

You can read more about the regulatory and ethical reviews in Modules 3, 4 and 5.



KEY WORDS

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.

Compensation:

Something, such as money, given as payment for injury or loss.

Confidentiality:

Keeping something private or secret.

Customs:

A practice followed by people of a particular group/community or region.

Enforced:

To cause to be carried out.

Dispute:

Conflict.

consent. Our Common Law can also be further developed by the courts in line with the Constitution, or Statute Law can replace the Common Law.

The areas of Common Law that are relevant to the HIV vaccine trials are:

- The Law of **Contract**: This governs agreements between trial participants and institutions running the trials. This could apply to the area of informed consent.
- The Law of **Delict**: This governs acts committed by people which harm others or their property. In HIV vaccine research and development this law could cover:
 - legal principles about **compensation** for research-related injury; and
 - rights to **confidentiality** and also informed consent.

Customary Law: These are written and unwritten laws which develop from the **customs** of a community. Customs become law when they are generally known by everyone in the community; they are generally followed by everyone in the community; and they are **enforced** in some way.

Court decisions: When people are involved in a **dispute** about the law, or when someone has broken the law, the dispute can go to the courts for a decision. This involves the courts interpreting the law in terms of the merits or concrete facts of the case.

DID YOU KNOW?

The court applies Common Law unless there is a Statute Law dealing with the issue. If Common Law is used, then it must be in agreement with the Constitution.



We have said that all laws must now be brought in line with our Constitution. This means that the courts will generally develop the law through their decisions, which must be in line with the human rights that are set out in our Bill of Rights. But before we had a Bill of Rights, apartheid laws were passed by an apartheid Parliament that was not representative of South African society. The courts, however, had to apply all the laws of the apartheid Parliament, even though some of these laws were in conflict with human rights that most other countries in the world followed.

Today, even if it were possible for our Parliament to pass laws that conflicted with our Bill of Rights, our courts have the power to strike them down.



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

Take 5 minutes ...

- Turn to the South African Bill of Rights in Appendix 1 on page 24. Which rights do you think are particularly important to HIV vaccine trial participants? Why are they important?
- How can these rights be violated in the HIV vaccine trials?
- How can these rights be respected, protected, promoted and fulfilled in the HIV vaccine trials?

Refer to Modules 4 and 7 for more information about criteria for trial participants and the process of trial participation.

The table which follows shows which human rights are most important to People Living with HIV or AIDS (PLWHAs). Many of these rights also apply to HIV vaccine trial participants, even those who are HIV-negative and who participate in preventative HIV vaccine clinical trials.

Section in Bill of Rights	Right	What this means for People Living with HIV and/or AIDS (PLWHAs), or for HIV vaccine trial participants
9	<p>EQUALITY</p> <p>Everyone has the right to equality and non-discrimination:</p> <ul style="list-style-type: none"> • Everyone is equal before the law and has the equal right to protection and benefit from the law. • No one may be unfairly discriminated against on grounds such as race, gender, sex, sexual orientation, disability, etc. 	No one may be unfairly discriminated against.
10	<p>HUMAN DIGNITY</p> <p>Everyone has the right to have their dignity respected and protected.</p>	No one may insult or damage any person's dignity, by their words or actions.
12(2)	<p>FREEDOM AND SECURITY OF THE PERSON</p> <p>Everyone has the right to:</p> <ul style="list-style-type: none"> • make decisions about pregnancy; • security and control over their body; and • not be subjected to medical or scientific experiments without their informed consent. 	People have the right to make their own decisions about medical treatment and pregnancy, e.g. you cannot be forced to test for HIV. HIV vaccine trial participants have a right to decide whether or not to participate in the trials.





Section in Bill of Rights	Right	What this means for People Living with HIV and/or AIDS (PLWHAs), or for HIV vaccine trial participants
14	PRIVACY Everyone has the right to privacy.	No one can force PLWHAs or trial participants to disclose their HIV status or any other information about themselves.
16	FREEDOM OF EXPRESSION Everyone has the right to freedom of expression. This includes freedom to receive or give out information or ideas.	Everyone should get proper information about how to prevent HIV – even people in schools or prisons.
18	FREEDOM OF ASSOCIATION Everyone has the right to freedom of association.	Anyone can join any organisation they choose.
21	FREEDOM OF MOVEMENT AND RESIDENCE 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	FREEDOM OF TRADE, OCCUPATION AND PROFESSION 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	LABOUR RELATIONS Everyone has the right to fair labour practices.	No one may be unfairly discriminated against at work.
24	ENVIRONMENT 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	HOUSING 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. They may not be evicted from a house or flat because of their health.





Section in Bill of Rights	Right	What this means for People Living with HIV and/or AIDS (PLWHAs), or for HIV vaccine trial participants
27	<p>HEALTH CARE, FOOD, WATER AND SOCIAL SECURITY</p> <p>Everyone has the right to have access to:</p> <ul style="list-style-type: none"> • health care services, including reproductive care; and • social security, including social assistance, if they cannot support themselves and their dependants. 	<ul style="list-style-type: none"> • No person may be refused emergency medical treatment. • Hospitals or doctors cannot refuse to treat a person with HIV or AIDS or someone who is participating in an HIV vaccine trial. • PLWHAs have the right to a Disability Grant if they are too ill to support themselves or their families.
29	<p>EDUCATION</p> <p>Everyone has the right to a basic education, including adult basic education.</p>	<p>PLWHAs have the same right as all people to education. A school cannot refuse to educate a person because she or he has HIV or AIDS.</p>
32	<p>ACCESS TO INFORMATION</p> <p>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 your rights.</p>	<ul style="list-style-type: none"> • 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 with private institutions (e.g. companies), and information that may be kept about you (e.g. your medical records). • People who are held in state institutions have the right to access to education and life-skills training on issues such as HIV and AIDS.
33	<p>JUST ADMINISTRATIVE ACTION</p> <p>Everyone whose rights have been negatively affected by administrative actions, has the right to be given written reasons.</p>	<p>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 these reasons in writing.</p>
35	<p>ARRESTED, DETAINED AND ACCUSED PERSONS</p> <p>Everyone who is detained, including every sentenced prisoner, has the right to conditions of detention that protect their dignity.</p>	<p>Prisoners cannot be treated in a discriminatory or undignified way just because of their HIV status.</p>

Adapted from *HIV/AIDS and the LAW (3rd edition)*



You will need to understand the following specific rights in more detail to help you present the draft *SAAVI Preventative HIV Vaccine Trial Participant Charter of Rights* to others:

- 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 who participates);
- the right to privacy and confidentiality; and
- the right of access to health care services.

The right to human dignity

The right to human dignity is central to the whole South African Constitution. The very first section of the Constitution says that South Africa is founded on the values of 'human dignity, the achievement of equality and the advancement of human rights and freedoms'. The right to human dignity is guaranteed in Section 10 of the Constitution and also underlies many other rights.

Why is dignity so important? Underlying the right to dignity is the idea that we need to recognise that every person has worth and value. Dignity is seen as the foundation on which many other rights are built. For example, the right to equality is built on the idea that every person has worth and must be treated with dignity and equality. And the right to informed consent is built on the idea that every person has worth and the ability to make individual choices or decisions.

"Recognising a right to dignity is an acknowledgement of the intrinsic worth of human beings: human beings are entitled to be treated as worthy of respect and concern. This right therefore is the foundation of many of the other rights that are specifically entrenched in the ... [Bill of Rights]."

Judge O'Reagan of the Constitutional Court in *S (State) v (versus) Makwanyane*



The South African Constitutional Court in session.



Human dignity also plays a very important role in clinical trials and is central to the draft *SAAVI Preventative HIV Vaccine Trial Participant Charter of Rights*. In clinical trials, the right to dignity emphasises that trial participants have inborn worth as human beings – they are not ‘guinea pigs’ or merely experimental data. They are not merely tools to help us find medical or scientific answers. Human beings must not be used as means to an end. Human beings are an end in themselves and have value.

The right to equality and non-discrimination

Take 5 minutes ...

- *Try to think of as many different types of discrimination experienced by People Living with HIV and/or AIDS (PLWHAs).*
- *Why do you think people reject, treat differently, or discriminate against PLWHAs?*
- *When do you think discrimination is unfair and illegal?*
- *What do you think ‘trial-related’ stigma and discrimination mean?*
- *Can you think of examples of when an HIV vaccine trial participant may experience stigma and discrimination, for example, in situations when there are strange or unpleasant reactions from friends or family who hear about their participation in the trial?*

Most of the different types of discrimination experienced by people living with HIV and/or AIDS happen out of fear and ignorance. Here are some examples:

- A person is dismissed from his or her job.
- A person is denied a job opportunity.
- A person is refused entry to a school.
- A person is denied life insurance.

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*). They list the following **grounds** on which discrimination can take place against anyone – race, gender, sex, pregnancy, marital status, ethnic or social origin, colour, sexual orientation, age, disability, religion, conscience, belief, culture, language and birth.

According to the law, you cannot discriminate against anyone on any of the above grounds. People have argued that HIV and AIDS can be seen as a disability and so no one may discriminate against someone on the grounds that they are living with HIV and/or AIDS. A trial participant may experience stigma and discrimination by people who find out that they are participating

KEY WORD

*Non-discrimination:
To not be discriminated
against.*

Refer to Module 5
for more information
on stigma and
discrimination.

KEY WORD

*Grounds:
Reasons.*



Refer to Module 5 for more information about the false-positive HIV antibody test result that may occur because of the test HIV vaccine.

KEY WORDS

Lawful:

Legal or not against the law.

Unlawful:

Illegal or against the law.

Refer to the *Did you know* box on page 16 for more information on the *International Covenant on Civil and Political Rights*.

in an HIV vaccine trial. Or, it is possible that a trial participant who tests false antibody-positive for HIV may experience the same kind of discrimination that a person who is living with HIV and/or AIDS may experience. Discrimination that is related to the person's participation in a trial is called trial-related stigma and discrimination.

How do we know when discrimination is unfair and unlawful and when it may be fair and lawful?

Earlier we said that our Constitution links the right to dignity to the right to equality. This leads to the idea that in a society as unequal as ours, to achieve equality, people may have to be treated differently or special measures may need to be put in place. For example, people who are vulnerable, at risk, or come from disadvantaged social, economic and political conditions, may need to be treated differently so that their right to equality can be fulfilled. So, sometimes discrimination is fair.

The law relating to equality and non-discrimination is one of the most difficult areas of law and unfortunately there is not enough space to discuss it here in great detail. The courts use a complicated test to decide whether or not unfair discrimination has occurred. They examine the social, economic and political conditions of the person or the group to see whether or not the right to equality is being violated. For our purposes it is useful to know that not all discrimination is **unlawful** or unfair. For example, normally in HIV vaccine trials it would not be unfair or unlawful to distinguish between people who are medically suited for the trials and those who are not. It would, however, be unfair discrimination to exclude women from the trials. And it is necessary to take special measures to ensure people's rights to equality, such as making sure that informed consent forms are available in the volunteer's language.

However, while the Constitution says that we may need to differentiate so that someone's right to equality is achieved, we cannot unfairly discriminate against someone – this is unlawful.

The right not to be subjected to medical or scientific experiments without (going through the process of) informed consent

The right to informed consent is contained in international law in the *International Covenant of Civil and Political Rights*. This right is also found in South African law in Section 12 (2) (c) of our Bill of Rights in the Constitution. It says:



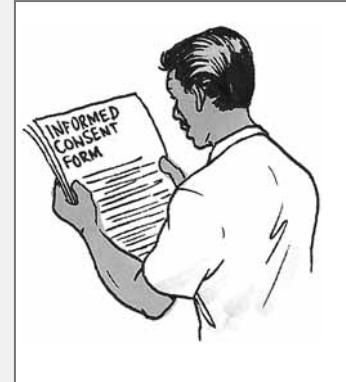
“Everyone has the right to bodily and psychological integrity, which includes the right –

- 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.”*

In other words, this section says that each person has a right to agree to participate or to refuse to participate in medical experiments or research, such as HIV vaccine research. This right says that medical experimentation (including vaccine research) without informed **consent** is unlawful and unconstitutional.

The requirement of informed consent is also described in our Common Law which says, informed consent means all of the following:

1. **Legal capacity:** In general, **adults** of 18 years and over, have the legal capacity to agree to participate in medical/scientific experimentation or research. At the moment, law-making bodies are still considering the age and the extent to which **children** have legal capacity to agree to participate in experimentation or research.
2. **Factual capacity:** People who agree to participate in experimentation or research, including HIV vaccine trials, must be ‘of sound mind’ so that they understand the facts, e.g. they must not be drunk or mentally ill.
3. **Lawful consent:** The consent must not be against the law or public policy. For example, based on our current scientific understanding, it would be against public policy to test a ‘live’ or attenuated HIV vaccine in clinical trials, as this type of design could cause HIV infection.
4. **Full information:** People need enough information about the research or procedures that they will go through and must understand what will happen if they give their consent to these procedures or if they refuse to give their consent. For example, people must be given enough information about the risks they face in the research so that they can make an informed decision based on this information. The consent form that trial participants need to sign to show their consent, should also be easy to understand, e.g. it should be written in plain language and should be available in a language that the person can easily understand.
5. **Free and voluntary:** People must not be forced to give their consent. They must give it freely and voluntarily. They are free to agree or not agree to take part.
6. **Freedom to withdraw:** People who give informed consent must be free to withdraw or take away that informed consent at any time.



Refer to Module 7 for information about the process of informed consent.

KEY WORDS

Consent:

Permission, approval, agreement.

Legal capacity:

The minimum age at which the law recognises your right to give permission for something.

Adult:

Anyone who is 18 years or older.

Children:

Anyone younger than 18 years.

Factual capacity:

‘Of sound mind’ so that the person understands the facts.

You can read more about different HIV vaccine designs in Module 4, and more about informed consent in Modules 4, 5 and 7.



DID YOU KNOW?

In 1948 after World War II, the international community through the United Nations, committed themselves to the 1948 Universal Declaration of Human Rights. This was seen as the first step in developing an International Bill of Human Rights.

The International Bill of Human Rights includes:

1. *The Universal Declaration of Human Rights.*
2. *The International Covenant on Economic, Social and Cultural Rights.*
3. *The International Covenant on Civil and Political Rights.*

South Africa is a signatory to the *International Covenant on Economic, Social and Cultural Rights*. It is also a signatory to and has ratified the *International Covenant on Civil and Political Rights*. Any country that is signatory to this covenant has a duty to protect a wide range of human rights, and must take the necessary steps to incorporate these rights into the legal and constitutional policies of its country. Article 7 of the *International Covenant on Civil and Political Rights* is relevant to HIV vaccine research. It says:

“No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.”



KEY WORDS

Civil court:

When the court sits to hear civil cases between individuals or parties, where the one party is claiming money from the other because of some damage or harm that was done.

Criminal court:

When the criminal court sits to hear criminal cases between the state and someone who has committed a crime.

Damages:

Compensation; the costs of.

Take time now to read through the case studies on informed consent in Section 2, pages 53–56. Each shows a different aspect of informed consent with a different group of people.

The right to privacy and confidentiality

Take 5 minutes ...

- Turn to page 60 to read the case study involving Mr McGeary.
- Think about or discuss the questions that appear on page 59.

What right was violated in the McGeary case and what action was taken?

Section 14 of our Bill of Rights in the Constitution includes the right to privacy. The Common Law also describes a right to privacy and a right to confidentiality. The McGeary case went to a **civil court** in 1993 – before the Constitution was adopted and so the court needed to refer to the Common Law. In this case, the court decided that according to the Common Law, Mr McGeary’s right to privacy and confidentiality was violated and he could claim **damages** from Dr Kruger.



Why is it important that we protect an HIV vaccine trial participant's right to privacy and confidentiality?

- The person may want to keep their participation in the trial and any other information about trial participation confidential for fear of **stigmatisation** and discrimination.
- A participant who becomes HIV-infected during a preventative HIV vaccine trial may want to keep this information confidential for the same reason.

When is the right to privacy and confidentiality not absolute? When is it limited?

- People themselves may decide to make certain information public. For example, they may decide to give an interview to a newspaper. Then they can no longer rely on the right to privacy.
- There may be other legislation that says that if certain sensitive information comes up during counselling, then the counsellor should report it to the appropriate authorities, for example, abuse of women or children.
- There may be a situation where someone is at risk and the potential harm can be avoided by making certain information available. For example, a trial participant in a preventative HIV vaccine trial becomes infected with HIV and tells a counsellor that he/she will not practice safe sex or tell his/her sexual partner. After trying different ways to work out the problem, as a last resort, the counsellor decides to tell the participant's sexual partner that the participant is HIV positive. It is unlikely that a court will say that the counsellor violated the trial participant's right to privacy. But the counsellor would have to show that she first tried to work out the problem by 'less restrictive means', for example, by counselling the trial participant on risk-reduction behaviour and offering to help disclose his/her status to the participant's sexual partner.

Take 5 minutes ...

- *An institution that conducts HIV vaccine trials only recruits people who are willing to give up their right to confidentiality about their participation in the trial. Is this a violation of the right to privacy?*

The answer is YES. No one may force a person to give up his or her right to confidentiality, unless the person voluntarily and freely agrees to do this.



KEY WORD

Stigmatisation:

Being described, seen or singled out, etc. as being someone who is bad or shameful.



The right to have access to health care services

All rights in Section 27 of the Constitution are socio-economic rights. Section 27 (1) (a) says that everyone has the right to have access to health care services. This right is part of the list of rights in Section 27 (1) which also describes people's rights to food, water and social security. Remember we said that these socio-economic rights cannot be claimed by individuals, but are rather seen as collective rights, for example, a group of people's right to housing, water, health care, education.

KEY WORDS

Negative duty:
The duty not to do something, e.g. not to interfere.

Positive duty:
The duty to do something, e.g. to take action.

The right to have access to health care services places a **negative duty** on the state – this means that the state must not interfere with anyone's enjoyment of health care services. This right also places a **positive duty** on the state – this means that the state must take all reasonable steps within the resources available to it, to progressively realise this access to health care for everyone in South Africa. These steps may include passing legislation or they may include other measures. The state must also draw up a plan and implement this plan to make sure that this right is realised for everyone.

Take 5 minutes ...

- *Can you think of some examples of when an HIV vaccine trial participant may need access to health care services?*



Throughout the trial the person may need counselling services.

Here are some examples of when a trial participant may need health care services:

- Throughout the trial the person may need counselling services to get information, to talk about his/her fears and concerns, etc.
- The person may need to go for HIV testing.
- The person may need treatment for an injury or illness that occurs during the HIV vaccine trial but is not necessarily related to the vaccine.
- The person may need HIV treatment if he/she becomes infected with HIV.

The rights and responsibilities of HIV vaccine trial participants are written into a document called the draft *SAAVI Preventative HIV Vaccine Trial Participant Charter of Rights*.



DID YOU KNOW?

A Charter or Bill is a document which sets out people's rights in a particular situation, e.g. a vaccine trial. For example, the *Patients Rights Charter* developed by the Department of Health, in 2001, says that for many years the majority of South Africans were denied their fundamental human rights, including the right to have access to health care services. Now, to make sure that all South Africans are guaranteed this fundamental right, the Department of Health has adopted the *Patients Rights Charter* to help support, promote and protect everyone's right to have access to health care services. This Charter lists patients' rights and responsibilities. It provides us with the standards that must be achieved so that the right of all South Africans to have access to health care services becomes a reality. There is a copy of the *Patients Rights Charter* in Appendix 2 on page 34.



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

Take 5 minutes ...

Quickly look through the draft Charter in Appendix 3, pages 36–38.

- How many sections or topics does it have?
- What do you think is included in each of the following sections:
 - Preamble
 - Informed consent
 - Non-discrimination and human dignity
 - The right to have access to health care services
 - The right to privacy
 - Responsibilities of trial participants

NOTE

The Charter that we are using in this Manual is the fourth draft, drawn up on 11 March 2004. The latest draft focuses on preventative HIV vaccine trials but much of it may be adopted to address therapeutic HIV vaccine trials and clinical trials in general.



KEY WORDS

Preamble:
Introduction.

Subscribers:
The people to whom the Charter applies.

No protective benefit:
In this situation it means that there is no guarantee that trial participants will be protected by the test preventative HIV vaccine from HIV or other risks.

Exploitation:
Abuse.

Disclosed:
Given.

Duration:
How long it will last.

The preamble

The preamble gives the background and introduction to the Charter and sets out what the **subscribers** would agree to, recognise and commit themselves to. Even though the Charter is not a legally binding document, the preamble also describes the legal and constitutional basis of the Charter.

Take 5 minutes ...

As you read through the preamble, think about these questions:

- *What does this mean: ‘even where **no protective benefit** from the test vaccine is guaranteed’?*
- *Can you think of an example of how medical and scientific experiments have led to the abuse or **exploitation** of people in the past?*
- *What processes must the researchers go through to get approval for clinical trials? (Refer to Modules 3 and 4 for more information.)*
- *What are the main points that subscribers are committing themselves to?*

Here is a brief overview of each section in the Charter.

Section 1: Informed consent to participate in the trial

Section 1 talks about the requirement of volunteers to give their informed consent to participate in the trials. It lists the information that must be **disclosed** to the volunteers so that they can make an informed decision about whether to participate or not. For example, information should be given about what the trial is about, what it involves, what phase of clinical trial that it is, and its **duration**. See Modules 5 and 7 for more information.

Section 2: Non-discrimination and human dignity

Section 2 deals with the participant’s rights to be treated with dignity and not to be discriminated against.

Section 3: The right of access to health care services

This section deals with every trial participant’s right to have continued free access to various health care services throughout the trial, e.g. counselling, testing and treatment.

Section 4: The right to privacy

Section 4 deals with the participant’s right to privacy and confidentiality. This includes the right to have information about them kept confidential. It explains when this right to confidentiality can be broken. Participants may also choose to be identified in another way for the purposes of this study.

Section 5: Responsibilities of trial participants

With rights come responsibilities. This section deals with the responsibilities of trial participants.



Take 5 minutes ...

As you read through each section of the Charter, think about these questions:

- Do you agree with all the **provisions** in the section? Which do you not agree with and why?
- Are all the provisions practical and realistic? Why or why not?
- Are the most important issues around informed consent covered? Which issues are left out? (Refer to Modules 5 and 7 for more information on informed consent.)
- Do you think the section favours the trial participants too much or the researchers too much, or is there a good balance?
- Will this section help someone think about their own rights and prepare them for participation in a trial?
- Which are the most useful provisions for trial participants, for communities affected by HIV and AIDS, and for other interested parties? How can the section be used to promote people's human rights?
- Which of these provisions apply to therapeutic HIV vaccine trial participants? What other provisions should be included for them?

TO SUM UP

- Human rights are rights and freedoms that everyone has, just because they are human. The state, individuals and other institutions have a duty to respect, protect, promote and fulfill human rights.
- In our Constitution, the human rights that are written into our Bill of Rights include civil, political and socio-economic human rights.
- 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 be adopted to address therapeutic HIV vaccine trials and clinical trials in general.

KEY WORD

*Provisions:
Terms, conditions.*



It is not only the human rights of trial participants that are affected by clinical research. The impact of clinical research raises broader human rights questions, some of which are explained in the activities, case studies and answers in Section 2 of this module.

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Useful websites

Human Rights Commission website: <http://www.sahrc.org.za>

Canadian HIV/AIDS Legal Network website:

<http://www.aidslaw.ca>, and look up vaccines

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South African Bill of Rights

Rights

7. 1. This Bill of Rights is a cornerstone of democracy in South Africa. It enshrines the rights of all people in our country and affirms the democratic values of human dignity, equality and freedom.
2. The state must respect, protect, promote and fulfil the rights in the Bill of Rights.
3. The rights in the Bill of Rights are subject to the limitations contained or referred to in section 36, or elsewhere in the Bill.

You can find the South African Bill of Rights at: www.info.gov.za/documents/constitution/index.htm.

Application

8. 1. The Bill of Rights applies to all law, and binds the legislature, the executive, the judiciary and all organs of state.
2. A provision of the Bill of Rights binds a natural or a juristic person if, and to the extent that, it is applicable, taking into account the nature of the right and the nature of any duty imposed by the right.
3. When applying a provision of the Bill of Rights to a natural or juristic person in terms of subsection (2), a court –
 - a. in order to give effect to a right in the Bill, must apply, or if necessary develop, the common law to the extent that legislation does not give effect to that right; and,
 - b. may develop rules of the common law to limit the right, provided that the limitation is in accordance with section 36(1).
4. A juristic person is entitled to the rights in the Bill of Rights to the extent required by the nature of the rights and the nature of that juristic person.

Equality

9. 1. Everyone is equal before the law and has the right to equal protection and benefit of the law.
2. Equality includes the full and equal enjoyment of all rights and freedoms. To promote the achievement of equality, legislative and other measures designed to protect or advance persons, or categories of persons, disadvantaged by unfair discrimination may be taken.
3. The state may not unfairly discriminate directly or indirectly against anyone on one or more grounds, including race, gender, sex, pregnancy, marital status, ethnic or social origin, colour, sexual orientation, age, disability, religion, conscience, belief, culture, language and birth.
4. No person may unfairly discriminate directly or indirectly against anyone on one or more grounds in terms of subsection (3). National legislation must be enacted to prevent or prohibit unfair discrimination.
5. Discrimination on one or more of the grounds listed in subsection (3) is unfair unless it is established that the discrimination is fair.

Human dignity

10. Everyone has inherent dignity and the right to have their dignity respected and protected.

Life

11. Everyone has the right to life.



Freedom and security of the person

12. 1. Everyone has the right to freedom and security of the person, which includes the right –
 - a. not to be deprived of freedom arbitrarily or without just cause;
 - b. not to be detained without trial;
 - c. to be free from all forms of violence from either public or private sources;
 - d. not to be tortured in any way; and,
 - e. not to be treated or punished in a cruel, inhuman or degrading way.
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.

Slavery, servitude and forced labour

13. No one may be subjected to slavery, servitude or forced labour.

Privacy

14. Everyone has the right to privacy, which includes the right not to have –
 - a. their person or home searched;
 - b. their property searched;
 - c. their possessions seized; or,
 - d. the privacy of their communications infringed.

Freedom of religion, belief and opinion

15. 1. Everyone has the right to freedom of conscience, religion, thought, belief and opinion.
2. Religious observances may be conducted at state or state-aided institutions, provided that –
 - a. those observances follow rules made by the appropriate public authorities,
 - b. they are conducted on an equitable basis; and,
 - c. attendance at them is free and voluntary.
3. a. This section does not prevent legislation recognising –
 - i. marriages concluded under any tradition, or a system of religious, personal or family law; or,
 - ii. systems of personal and family law under any tradition, or adhered to by persons professing a particular religion.
- b. Recognition in terms of paragraph (a) must be consistent with this section and the other provisions of the Constitution.

Freedom of expression

16. 1. Everyone has the right to freedom of expression, which includes –
 - a. freedom of the press and other media;
 - b. freedom to receive or impart information or ideas;
 - c. freedom of artistic creativity; and,
 - d. academic freedom and freedom of scientific research.
2. The right in subsection (1) does not extend to –
 - a. propaganda for war;
 - b. incitement of imminent violence; or,
 - c. advocacy of hatred that is based on race, ethnicity, gender or religion, and that constitutes incitement to cause harm.



Assembly, demonstration, picket and petition

17. Everyone has the right, peacefully and unarmed, to assemble, to demonstrate, to picket and to present petitions.

Freedom of association

18. Everyone has the right to freedom of association.

Political rights

19. 1. Every citizen is free to make political choices, which includes the right –
- a. to form a political party;
 - b. to participate in the activities of, or recruit members for, a political party, and,
 - c. to campaign for a political party or cause.
2. Every citizen has the right to free, fair and regular elections for any legislative body established in terms of the Constitution.
3. Every adult citizen has the right –
- a. to vote in elections for any legislative body established in terms of the Constitution, and to do so in secret; and,
 - b. to stand for public office and, if elected, to hold office.

Citizenship

20. No citizen may be deprived of citizenship.

Freedom of movement and residence

21. 1. Everyone has the right to freedom of movement.
- 2. Everyone has the right to leave the Republic.
 - 3. Every citizen has the right to enter, to remain in and to reside anywhere in, the Republic.
 - 4. Every citizen has the right to a passport.

Freedom of trade, occupation and profession

22. Every citizen has the right to choose their trade, occupation or profession freely. The practice of a trade, occupation or profession may be regulated by law.

Labour relations

23. 1. Everyone has the right to fair labour practices.
- 2. Every worker has the right –
 - a. to form and join a trade union;
 - b. to participate in the activities and programmes of a trade union; and,
 - c. to strike.
 - 3. Every employer has the right –
 - a. to form and join an employers' organisation; and,
 - b. to participate in the activities and programmes of an employers' organisation.
 - 4. Every trade union and every employers' organisation has the right –
 - a. to determine its own administration, programmes and activities;
 - b. to organise; and,
 - c. to form and join a federation.



5. Every trade union, employers' organisation and employer has the right to engage in collective bargaining. National legislation may be enacted to regulate collective bargaining. To the extent that the legislation may limit a right in this Chapter, the limitation must comply with section 36(1).
6. National legislation may recognise union security arrangements contained in collective agreements. To the extent that the legislation may limit a right in this Chapter, the limitation must comply with section 36(1).

Environment

24. Everyone has the right –
 - a. to an environment that is not harmful to their health or well-being; and,
 - b. to have the environment protected, for the benefit of present and future generations, through reasonable legislative and other measures that –
 - i. prevent pollution and ecological degradation;
 - ii. promote conservation; and,
 - iii. secure ecologically sustainable development and use of natural resources while promoting justifiable economic and social development.

Property

25. 1. No one may be deprived of property except in terms of law of general application, and no law may permit arbitrary deprivation of property.
2. Property may be expropriated only in terms of law of general application –
 - a. for a public purpose or in the public interest; and,
 - b. subject to compensation, the amount of which and the time and manner of payment of which have either been agreed to by those affected or decided or approved by a court.
3. The amount of the compensation and the time and manner of payment must be just and equitable, reflecting an equitable balance between the public interest and the interests of those affected, having regard to all relevant circumstances, including –
 - a. the current use of the property;
 - b. the history of the acquisition and use of the property;
 - c. the market value of the property;
 - d. the extent of direct state investment and subsidy in the acquisition and beneficial capital improvement of the property; and,
 - e. the purpose of the expropriation.
4. For the purposes of this section –
 - a. the public interest includes the nation's commitment to land reform, and to reforms to bring about equitable access to all South Africa's natural resources; and,
 - b. property is not limited to land.
5. The state must take reasonable legislative and other measures, within its available resources, to foster conditions, which enable citizens to gain access to land on an equitable basis.
6. A person or community whose tenure of land is legally insecure as a result of past racially discriminatory laws or practices is entitled, to the extent provided by an Act of Parliament, either to tenure which is legally secure or to comparable redress.
7. A person or community dispossessed of property after 19 June 1913 as a result of past racially discriminatory laws or practices is entitled, to the extent provided by an Act of Parliament, either to restitution of that property or to equitable redress.
8. No provision of this section may impede the state from taking legislative and other measures to achieve land, water and related reform, in order to redress the results of past racial discrimination, provided that any departure from the provisions of this section is in accordance with the provisions of section 36(1).
9. Parliament must enact the legislation referred to in subsection (6).



Housing

26. 1. Everyone has the right to have access to adequate housing.
2. The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of this right.
3. No one may be evicted from their home, or have their home demolished, without an order of court made after considering all the relevant circumstances. No legislation may permit arbitrary evictions.

Health care, food, water and social security

27. 1. Everyone has the right to have access to –
a. health care services, including reproductive health care;
b. sufficient food and water; and,
c. social security, including, if they are unable to support themselves and their dependants, appropriate social assistance.
2. The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.
3. No one may be refused emergency medical treatment.

Children

28. 1. Every child has the right –
a. to a name and a nationality from birth;
b. to family care or parental care, or to appropriate alternative care when removed from the family environment;
c. to basic nutrition, shelter, basic health care services and social services;
d. to be protected from maltreatment, neglect, abuse or degradation;
e. to be protected from exploitative labour practices;
f. not to be required or permitted to perform work or provide services that –
i. are inappropriate for a person of that child's age; or,
ii. place at risk the child's well-being, education, physical or mental health or spiritual, moral or social development;
g. not to be detained except as a measure of last resort, in which case, in addition to the rights a child enjoys under sections 12 and 35, the child may be detained only for the shortest appropriate period of time, and has the right to be –
i. kept separately from detained persons over the age of 18 years; and,
ii. treated in a manner, and kept in conditions that take account of the child's age;
h. to have a legal practitioner assigned to the child by the state, and at state expense, in civil proceedings affecting the child, if substantial injustice would otherwise result; and,
i. not to be used directly in armed conflict, and to be protected in times of armed conflict.
2. A child's best interests are of paramount importance in every matter concerning the child.
3. In this section "child" means a person under the age of 18 years.

Education

29. 1. Everyone has the right –
a. to a basic education, including adult basic education; and,
b. to further education, which the state, through reasonable measures, must make progressively available and accessible.



2. Everyone has the right to receive education in the official language or languages of their choice in public educational institutions where that education is reasonably practicable. In order to ensure the effective access to, and implementation of, this right, the state must consider all reasonable educational alternatives, including single medium institutions, taking into account –
 - a. equity;
 - b. practicability; and,
 - c. the need to redress the results of past racially discriminatory laws and practices.
3. Everyone has the right to establish and maintain, at their own expense, independent educational institutions that –
 - a. do not discriminate on the basis of race;
 - b. are registered with the state; and,
 - c. maintain standards that are not inferior to standards at comparable public educational institutions.
4. Subsection (3) does not preclude state subsidies for independent educational institutions.

Language and culture

30. Everyone has the right to use the language and to participate in the cultural life of their choice, but no one exercising these rights may do so in a manner inconsistent with any provision of the Bill of Rights.

Cultural, religious and linguistic communities

31. 1. Persons belonging to a cultural religious or linguistic community may not be denied the right, with other members of that community –
 - a. to enjoy their culture, practice their religion and use their language; and,
 - b. to form, join and maintain cultural, religious and linguistic associations and other organs of civil society.
2. The rights in subsection (1) may not be exercised in a manner inconsistent with any provision of the Bill of Rights.

Access to information

32. 1. Everyone has the right of access to –
 - a. any information held by the state; and,
 - b. any information that is held by another person and that is required for the exercise or protection of any rights.
2. National legislation must be enacted to give effect to this right, and may provide for reasonable measures to alleviate the administrative and financial burden on the state.

Just administrative action

33. 1. Everyone has the right to administrative action that is lawful, reasonable and procedurally fair.
2. Everyone whose rights have been adversely affected by administrative action has the right to be given written reasons.
3. National legislation must be enacted to give effect to these rights, and must –
 - a. provide for the review of administrative action by a court or, where appropriate, an independent and impartial tribunal;
 - b. impose a duty on the state to give effect to the rights in subsections (1) and (2); and,
 - c. promote an efficient administration.



Access to courts

34. Everyone has the right to have any dispute that can be resolved by the application of law decided in a fair public hearing before a court or, where appropriate, another independent and impartial tribunal or forum.

Arrested, detained and accused persons

35. 1. Everyone who is arrested for allegedly committing an offence has the right –
- a. to remain silent;
 - b. to be informed promptly –
 - i. of the right to remain silent; and
 - ii. of the consequences of not remaining silent;
 - c. not to be compelled to make any confession or admission that could be used in evidence against that person;
 - d. to be brought before a court as soon as reasonably possible, but not later than –
 - i. 48 hours after the arrest; or
 - ii. the end of the first court day after the expiry of the 48 hours, if the 48 hours expire outside ordinary court hours or on a day which is not an ordinary court day;
 - e. at the first court appearance after being arrested, to be charged or to be informed of the reason for the detention to continue, or to be released; and
 - f. to be released from detention if the interests of justice permit, subject to reasonable conditions.
2. Everyone who is detained, including every sentenced prisoner, has the right –
- a. to be informed promptly of the reason for being detained;
 - b. to choose, and to consult with, a legal practitioner, and to be informed of this right promptly;
 - c. to have a legal practitioner assigned to the detained person by the state and at state expense, if substantial injustice would otherwise result, and to be informed of this right promptly;
 - d. to challenge the lawfulness of the detention in person before a court and, if the detention is unlawful, to be released;
 - e. to conditions of detention that are consistent with human dignity, including at least exercise and the provision, at state expense, of adequate accommodation, nutrition, reading material and medical treatment; and,
 - f. to communicate with, and be visited by, that person's –
 - i. spouse or partner;
 - ii. next of kin;
 - iii. chosen religious counsellor; and
 - iv. chosen medical practitioner.
3. Every accused person has a right to a fair trial, which includes the right –
- a. to be informed of the charge with sufficient detail to answer it;
 - b. to have adequate time and facilities to prepare a defence;
 - c. to a public trial before an ordinary court;
 - d. to have their trial begin and conclude without unreasonable delay;
 - e. to be present when being tried;
 - f. to choose, and be represented by, a legal practitioner, and to be informed of this right promptly;
 - g. to have a legal practitioner assigned to the accused person by the state and at state expense, if substantial injustice would otherwise result, and to be informed of this right promptly;
 - h. to be presumed innocent, to remain silent, and not to testify during the proceedings;
 - i. to adduce and challenge evidence;
 - j. not to be compelled to give self-incriminating evidence;



- k. to be tried in a language that the accused person understands or, if that is not practicable, to have the proceedings interpreted in that language;
 - l. not to be convicted for an act or omission that was not an offence under either national or international law at the time it was committed or omitted;
 - m. not to be tried for an offence in respect of an act or omission for which that person has previously been either acquitted or convicted;
 - n. to the benefit of the least severe of the prescribed punishments if the prescribed punishment for the offence has been changed between the time that the offence was committed and the time of sentencing; and,
 - o. of appeal to, or review by, a higher court.
4. Whenever this section requires information to be given to a person, that information must be given in a language that the person understands.
 5. Evidence obtained in a manner that violates any right in the Bill of Rights must be excluded if the admission of that evidence would render the trial unfair or otherwise be detrimental to the administration of justice.

Limitation of rights

36. 1. The rights in the Bill of Rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors, including –
 - a. the nature of the right;
 - b. the importance of the purpose of the limitation;
 - c. the nature and extent of the limitation;
 - d. the relation between the limitation and its purpose; and,
 - e. less restrictive means to achieve the purpose.
2. Except as provided in subsection (1) or in any other provision of the Constitution, no law may limit any right entrenched in the Bill of Rights.

States of emergency

37. 1. A state of emergency may be declared only in terms of an Act of Parliament, and only when –
 - a. the life of the nation is threatened by war, invasion, general insurrection, disorder, natural disaster or other public emergency; and,
 - b. the declaration is necessary to restore peace and order.
2. A declaration of a state of emergency, and any legislation enacted or other action taken in consequence of that declaration, may be effective only –
 - a. prospectively; and,
 - b. for no more than 21 days from the date of the declaration, unless the National Assembly resolves to extend the declaration. The Assembly may extend a declaration of a state of emergency for no more than three months at a time. The first extension of the state of emergency must be by a resolution adopted with a supporting vote of a majority of the members of the Assembly. Any subsequent extension must be by a resolution adopted with a supporting vote of at least 60 per cent of the members of the Assembly. A resolution in terms of this paragraph may be adopted only following a public debate in the Assembly.
3. Any competent court may decide on the validity of –
 - a. a declaration of a state of emergency;
 - b. any extension of a declaration of a state of emergency; or,
 - c. any legislation enacted, or other action taken, in consequence of a declaration of a state of emergency.



4. Any legislation enacted in consequence of a declaration of a state of emergency may derogate from the Bill of Rights only to the extent that –
 - a. the derogation is strictly required by the emergency; and,
 - b. the legislation –
 - i. is consistent with the Republic’s obligations under international law applicable to states of emergency;
 - ii. conforms to subsection (5); and,
 - iii. is published in the national Government Gazette as soon as reasonably possible after being enacted.
5. No Act of Parliament that authorises a declaration of a state of emergency, and no legislation enacted or other action taken in consequence of a declaration, may permit or authorise –
 - a. indemnifying the state, or any person, in respect of any unlawful act;
 - b. any derogation from this section; or,
 - c. any derogation from a section mentioned in column 1 of the Table of Non-Derogable Rights (below), to the extent indicated opposite that section in column 3 of the Table.

Section no.	Section title	Extent to which the right is protected
9	Equality	With respect to unfair discrimination solely on the grounds of race, colour, ethnic or social origin, sex, religion or language
10	Human dignity	Entirely
11	Life	Entirely
12	Freedom and security of the person	With respect to subsections (1)(d) and (e) and (2)(c).
13	Slavery, servitude and forced labour	With respect to slavery and servitude
28	Children	With respect to: <ul style="list-style-type: none"> • subsection (1)(d) and (e); • the rights in subparagraphs (i) and (ii) of subsection (1)(g); and • subsection 1(i) in respect of children of 15 years and younger
35	Arrested, detained and accused persons	With respect to: <ul style="list-style-type: none"> • subsections (1)(a), (b) and (c) and (2)(d); • the rights in paragraphs (a) to (o) of subsection (3), excluding paragraph (d) • subsection (4); and • subsection (5) with respect to the exclusion of evidence if the admission of that evidence would render the trial unfair.

6. Whenever anyone is detained without trial in consequence of a derogation of rights resulting from a declaration of a state of emergency, the following conditions must be observed:
 - a. An adult family member or friend of the detainee must be contacted as soon as reasonably possible, and informed that the person has been detained.
 - b. A notice must be published in the national Government Gazette within five days of the person being detained, stating the detainee’s name and place of detention and referring to the emergency measure in terms of which that person has been detained.



- c. The detainee must be allowed to choose, and be visited at any reasonable time by, a medical practitioner.
 - d. The detainee must be allowed to choose, and be visited at any reasonable time by, a legal representative.
 - e. A court must review the detention as soon as reasonably possible, but no later than 10 days after the date the person was detained, and the court must release the detainee unless it is necessary to continue the detention to restore peace and order.
 - f. A detainee who is not released in terms of a review under paragraph (e), or who is not released in terms of a review under this paragraph, may apply to a court for a further review of the detention at any time after 10 days have passed since the previous review, and the court must release the detainee unless it is still necessary to continue the detention to restore peace and order.
 - g. The detainee must be allowed to appear in person before any court considering the detention, to be represented by a legal practitioner at those hearings, and to make representations against continued detention.
 - h. The state must present written reasons to the court to justify the continued detention of the detainee, and must give a copy of those reasons to the detainee at least two days before the court reviews the detention.
7. If a court releases a detainee, that person may not be detained again on the same grounds unless the state first shows a court good cause for re-detaining that person.
8. Subsections (6) and (7) do not apply to persons who are not South African citizens and who are detained in consequence of an international armed conflict. Instead, the state must comply with the standards binding on the Republic under international humanitarian law in respect of the detention of such persons.

Enforcement of rights

38. Anyone listed in this section has the right to approach a competent court, alleging that a right in the Bill of Rights has been infringed or threatened, and the court may grant appropriate relief, including a declaration of rights. The persons who may approach a court are –
- a. anyone acting in their own interest;
 - b. anyone acting on behalf of another person who cannot act in their own name;
 - c. anyone acting as a member of, or in the interest of, a group or class of persons;
 - d. anyone acting in the public interest; and
 - e. an association acting in the interest of its members.

Interpretation of Bill of Rights

39. 1. When interpreting the Bill of Rights, a court, tribunal or forum –
- a. must promote the values that underlie an open and democratic society based on human dignity, equality and freedom;
 - b. must consider international law; and
 - c. may consider foreign law.
2. When interpreting any legislation, and when developing the common law or customary law, every court, tribunal or forum must promote the spirit, purport and objects of the Bill of Rights.
3. The Bill of Rights does not deny the existence of any other rights or freedoms that are recognised or conferred by common law, customary law or legislation, to the extent that they are consistent with the Bill.



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.
- 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 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



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-imbursment 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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Section 2: Activities to help you present information on legal and human rights and HIV vaccines to others

OVERALL OUTCOMES

By the end of these activities, workshop participants should be able to:

1. Describe what human rights are.
2. Explain different kinds of human rights.
3. Describe what legal rights are.
4. Identify which rights are important to HIV vaccine trial participants and why.
5. Discuss how the draft *SAAVI Preventative HIV Vaccine Trial Participant Charter of Rights* tries to raise awareness about the rights of trial participants.

ACTIVITY 1: WHAT ARE LEGAL AND HUMAN RIGHTS?

OUTCOMES OF THIS ACTIVITY

By the end of this activity, workshop participants should be able to:

- Explain what they understand by human and legal rights.
- Describe how human rights can be abused.
- Explain which rights are important to HIV vaccine trial participants.

MATERIALS NEEDED

- See the checklist of resources needed on page 7 of Module 1.
- Copies of the *HIV Vaccines Learner's Handbook* or pages 2–8 of this module.
- Overheads to discuss what human rights are, how they are ensured, the different kinds of human rights, civil and political rights, socio-economic rights, and legal rights.
- You need four blank flashcards for each workshop participant and flipchart paper.

TIME: 70 minutes for Parts 1 and 2 of this activity. If time is limited, then go straight to Part 2.

Part 1: To find out what workshop participants already know about human rights

PREPARATION

- Read through Section 1, pages 2–8 of this module.
- Prepare four pieces of flipchart paper, labelled as follows:
 - *Flipchart 1: What is a human right?*
 - *Flipchart 2: How can human rights be abused?*

NOTE

For copies of the *HIV Vaccines Learner's Handbook* or overheads for the Activities, please contact *Masikhulisane* who will send you an electronic copy of the document. You can use the document to print the pages that you need as this may be easier and less costly than photocopying notes from Section 1 of the Manual.

REMEMBER!

Use the *HIV Vaccines Learner's Handbook* where appropriate for these activities.



- *Flipchart 3: Which human rights are important to People Living with HIV and/or AIDS?*
- *Flipchart 4: Which human rights are important to HIV vaccine trial participants?*
- Make photocopies of any handouts needed (see process notes).

PROCESS

1. Workshop participants work on their own or in pairs. Give each person four blank flashcards and ask them to do the following:
 - a) On the first flashcard write an example of a human right, and a sentence explaining what a human right is. For example: *Everyone has the right to life. Human rights are rights that belong to us because we are human.*
 - b) On the second flashcard, write an example of how, in your experience a human right has been abused. For example: *My right to freedom of expression was abused when I was beaten by a police officer at a protest meeting.*
 - c) On the third flashcard, write an example of a human right that is relevant to a person living with HIV and/or AIDS. For example: *People Living with HIV and/or AIDS have the right to privacy.*
 - d) On the fourth flashcard, write an example of a human right that is relevant to an HIV vaccine trial participant. For example: *Trial participants have the right to confidentiality.*
2. Ask people to stick their flashcards up on the relevant flipchart paper.
3. Now work as a whole group. Ask someone to read out the flashcards on each flipchart.
4. Sum up the ideas on each flipchart and fill in any gaps using your overheads.
5. Refer participants to the *HIV Vaccines Learner's Handbook*, or give them copies of pages 2–8 of Section 1 for information covered in this activity.

REMEMBER!

Be sensitive to the literacy levels of workshop participants. If you think someone is illiterate, then rather work in pairs or small groups, making sure there is at least one literate person in the pair. Or, use more oral discussion and role-plays.

Part 2: For more in-depth discussion

PREPARATION

- Read through Section 1, pages 2–8 and prepare to give input on the information.
- Use the overheads mentioned below.
- Make photocopies of any handouts needed (see process notes).

PROCESS

1. Give input on the following (use your overheads):
 - human rights in the Bill of Rights of the Constitution, including civil and economic rights and socio-economic rights; and
 - legal rights.



2. Finally, if you have time, take examples from the three flipcharts completed in Part 1 of this activity (if you did Part 1) and analyse what kinds of rights are involved.
3. Refer participants to the *HIV Vaccines Learner's Handbook*, or give them copies of pages 2–8 of Section 1 for information covered in this activity.

ACTIVITY 2: WHICH RIGHTS ARE IMPORTANT TO HIV VACCINE TRIAL PARTICIPANTS?

OUTCOMES OF THIS ACTIVITY

By the end of this activity, workshop participants should be able to:

- Identify which human rights are important to HIV vaccine trial participants and how they are important.
- Describe how these rights can be violated.
- Explain how these rights can be enforced.

MATERIALS NEEDED

- See the checklist of resources needed on page 7 of Module 1.
- Copies of the *HIV Vaccines Learner's Handbook* or photocopies of pages 9–19 of Section 1.
- Use overheads on the rights that are important to people living with HIV and AIDS, and the rights that are relevant to HIV vaccine trial participants.
- You need photocopies of the Bill of Rights in the South African Constitution for each workshop participant (see Appendix 1 at the end of Section 1).

TIME: 60 minutes

PREPARATION

- Read Section 1, pages 9–19 of this module.
- Where necessary, photocopy the South African Bill of Rights in Appendix 1 at the end of Section 1 for each workshop participant. The South African Bill of Rights is available online at www.gov.za under the link called Constitution. The Government Printers may also be able to give you copies of the Bill.
- Copy the table in Step 2 on page 42 onto flipchart paper.
- Make photocopies of any handouts needed (see process notes).

PROCESS

1. Workshop participants work in small groups. Ask each group to read through their copy of the Bill of Rights and then to choose those rights that they think apply to HIV vaccine trial participants.

Remind participants to elect a group leader, timekeeper and a rapporteur to report back to the plenary session. See Module 1 to remind yourself about processes we use in group work.



2. Ask each group to copy the following table onto flipchart paper:

Rights that are important to HIV vaccine trial participants	How these rights could be violated in an HIV vaccine trial	How these rights can be ensured in an HIV vaccine trial

- In Column 1 of their table, each group lists the rights they have chosen. They can simply write the title of the right, e.g. labour relations.
 - In Column 2 they list the ways in which each of these rights could be violated in an HIV vaccine trial.
 - In Column 3 they write how we can ensure each of these rights for HIV vaccine trial participants. For example, if researchers have disclosed medical information about a trial participant, then the trial participant, as a first step, can complain to the ethics committee which is reviewing the research, or the Human Rights Commission. It may be even possible to take legal action, as a last resort.
3. When everyone has finished, ask each group to report back to the plenary.
 4. Briefly discuss in plenary which rights may be more relevant to preventative HIV vaccine trials, and to therapeutic HIV vaccine trials.
 5. Sum up by reminding everyone that because these rights are now written into the Constitution they must be respected, promoted, protected and fulfilled or enforced by the courts. (Use the relevant overheads.)
 6. Refer participants to the *HIV Vaccines Learner's Handbook*, or give them copies of pages 9–19 of Section 1 for information covered in this activity.

ACTIVITY 3: HOW CAN WE APPLY HUMAN RIGHTS TO PRACTICAL SITUATIONS THAT MAY ARISE DURING HIV VACCINE TRIALS?

OUTCOMES OF THIS ACTIVITY

By the end of this activity, workshop participants should be able to:

- Relate their knowledge of human rights to practical situations that may arise during the HIV vaccine trials.
- Explain how to promote and protect human rights.

MATERIALS NEEDED

- See the checklist of resources needed on page 7 of Module 1.
- Photocopies of pages 44 to 45, and if necessary pages 46–47,



if you are doing Part 1 of this Activity. Make photocopies of the role-play scenarios on pages 49–51 if you are doing Part 2.

TIME: 60 minutes for Part 1 of this activity. Part 2 is an extension activity that you can do with more advanced groups. It takes about 60–90 minutes.

Part 1: Applying human rights to practical situations

PREPARATION

- Read through what people are saying on pages 44–45 and read the *Possible answers* on pages 46–47.
- Photocopy the five scenarios for workshop participants.
- Prepare the following questions on the flipchart:
 - *Have any human rights or principles of law been violated? If so, which ones?*
 - *What advice would you give to prevent this situation from happening or to work through the problem?*

PROCESS

1. Work in pairs. Give each pair a copy of one of the scenarios to work on. Explain that these situations are not real but are simply examples of what could happen.
2. Ask the pairs to read what the person in their scenario is saying and then to discuss the questions. They can record their points on flipchart paper.
3. Once each pair is finished discussing their scenario, come back to plenary and ask a few pairs to present their answers.
4. Sum up the discussion by mentioning the rights or principles of the law that have been violated, as well as possible remedies. Use the *Possible answers* that follow for solutions.
5. Workshop participants may want photocopies of the scenarios and answers on pages 44–47.

NOTE

You may need to summarise the aims of the different phases in the HIV vaccine clinical trials and run through these quickly with the group before doing the next few activities. Use information from Module 4.



Scenario 1

I am Mpbo. I am participating in an HIV vaccine trial. The other day I was reading the newspaper when I saw an article in which the researchers described the trial participants as 'guinea pigs'. I am angry because I feel that my right to dignity has been violated.



Scenario 2



My name is David and I am on the Community Advisory Group (CAG). The city has demanded that researchers give us all the names of people participating in the HIV vaccine trial otherwise we will prevent the community from participating. The researchers have refused and we do not know why.

Scenario 3

I am Loretta. I have volunteered to participate in a phase I preventative HIV vaccine trial. After the trial began and I received the vaccine, I applied for life cover from an insurance company. They had me tested for HIV. But, my body has developed an immune response to the harmless bits of HIV used in the vaccine and I have antibodies to these bits, which the test picked up. I know I do not have the virus, but now the insurance company refuses to give me life cover.





Scenario 4



I am Noel. For the past five months I have been part of a phase III preventative HIV vaccine trial. The other day I tested positive for HIV. So I went to the local radio station and told everyone that the trial is dangerous and causes people to get HIV. I told them that all the researchers ever told me was that it was safe. How do I know what they injected into me? I have not had unprotected sex for years.

Scenario 5

I am Sarah. A phase I HIV vaccine trial has just begun in my community and already a number of participants are experiencing serious adverse events. One person died. Our community suspects that the cause of the illnesses and the death may be the test HIV vaccine.



KEY WORDS

Adverse Event (AE):
Any untoward medical occurrence in a patient or trial participant who is given a pharmaceutical product. The untoward medical occurrence is not necessarily caused by the pharmaceutical product. So an AE can be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease, temporarily associated with the use of an investigational product, whether or not these are related to the investigational product.

Serious adverse event (SAE):
An AE that results in one or more of the following: death; a life-threatening condition; hospitalisation; an ongoing or significant disability/incapacity; or a birth defect.



POSSIBLE ANSWERS FOR SCENARIOS

NOTE

Only use these guiding answers to summarise the legal position. However, do not limit the discussion to the legal position, but encourage broader discussion of the human rights implications of these case studies.

Scenario 1: Mpho

This statement about ‘guinea pigs’ may violate the trial participants’ right to dignity, by comparing them to animals which are often used only for medical experiments. Section 10 of the Constitution states that everyone has the right to dignity and the right to have their dignity respected and protected. Unfortunately, it is unlikely that the researcher can be taken to court for this statement. The statement is hurtful, and it discourages others from participating in important future research. Such statements must be discouraged by teaching people about the importance and dignity of human participation in medical research. If a statement like this is made, organisations like the CAGs or Research Ethics Committees have an important role to play in persuading the speaker to apologise or to rephrase the statement.

Scenario 2: David

Everyone has a right to confidentiality regarding their medical treatment, which includes their participation in the trial. (This is both a human right in the Bill of Rights and a Common Law right). If the researchers reveal trial participants’ names, participants may take the research institution to court and sue for damages. A research institution cannot insist that participants give up their right to privacy in order to participate. However, there may be situations where trial participants agree that information regarding their participation can be made public. For example, by giving an interview about the experience as a trial participant to the media and allowing their photo to be taken.

Scenario 3: Loretta

- The insurance company’s refusal to insure Loretta may be unfair discrimination in terms of the equality clause in the Constitution and may also violate the Promotion of Equality and Prevention of Unfair Discrimination Act (and so involve the Equality Court).
- The Life Offices’ Association (LOA) deals with most of the life insurance companies in South Africa. After a request from the SAAVI, the Association changed their HIV testing rules with regard to HIV vaccine trial participants who apply for insurance.

Refer to Module 5 for more information about the Life Offices’ Association (LOA).



If trial participants in a preventative HIV vaccine trial test antibody-positive on the standard HIV antibody tests, the insurance companies (regulated by the Life Offices' Association (LOA) of South Africa) now pay for a second different HIV test to be given. This test can tell the difference between real infection and the antibody immune reaction that may be caused by the test vaccine.

Scenario 4: Noel

The courts will probably not be able to resolve this situation, so other steps must be taken to prevent what is false information about the vaccine and the risks of trial participation. According to the *Medicines and Related Substances Control Act* of 1965, the Medicines Control Council (MCC) ensures that an HIV vaccine is 'in the public interest', especially in respect of scientific and safety aspects. At present the HIV vaccines that are being tested in humans cannot cause HIV infection. Trial participants should have been given full information about this during the informed consent process. Noel could also be giving false information about not having had unprotected sex. There may be a role for the CAG to resolve this issue.

Scenario 5: Sarah

It is very unlikely that serious adverse events (SAEs) will be experienced during a clinical trial. However, if they are, this still does not necessarily mean that the death was caused by the test vaccine. The cause of death may have been due to natural causes and be totally unrelated to the test vaccine. Serious adverse events are monitored by the parties involved in running trials and, apart from this, an enquiry would be held into the reasons for any unnatural death. But the risk of such adverse events is generally considered to be very low.

In South Africa, before approval for a trial is given, the Sponsor of the trial must take out insurance for compensation of research-related injuries. This is a requirement of the *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa, Clinical Trials Guidelines, 2000*.

As a last resort, according to the Common Law of Delict, if the wrongful actions of one person (the institution conducting the trial) cause harm to another person, the wrongdoer must compensate for the harm (usually by paying money). In this case, it must first be proven that the vaccine caused the serious adverse event of death. It also must be proven that the research institution was careless in their preparation or administration of the vaccine. It would be difficult to prove these things. However, the strength of the case would depend on the particular circumstances.



You can read more about role-plays and how to set them up in Module 1.

Only do this activity if you have time or with an advanced group.

Part 2: Extension activity on human rights

PREPARATION

- Read through the role-plays on pages 49–51 of this module.
- Photocopy the role-plays for the workshop participants (there will be three groups, each dealing with one role-play). You might want to adapt some of the role-plays so that they also focus on therapeutic trials.
- Write up the following questions on flipchart paper:
 - *What are the good points in the situation?*
 - *Which human rights are being ensured in the trial and how?*
 - *Which human rights are being violated and how?*
 - *What should the researchers do to make sure that these human rights are not violated?*
 - *From a human rights point of view, should the trial be conducted?*
- Make photocopies of any handouts needed (see process notes).

PROCESS

1. Work in three groups. Assign each group one of the role-plays to prepare by giving them copies of the relevant scenario. Each person in the group must be given a role to act out. Give them 30 minutes to read through and prepare a 10-minute role-play.
2. Give each group a chance to do their role-plays. Each group should make sure that in their role-play they clearly bring out or answer the questions that you prepared on flipchart.
3. After the role-plays, ask participants to discuss if the role-play clearly showed or answered these questions. Use their ideas to discuss how the human rights issues can be addressed.



ROLE-PLAY 1 – PHASE I TRIAL

A research hospital has received funding for a phase I preventative HIV vaccine trial.

You need the following role-players:

- Researchers
- Community members
- A newspaper reporter

The researchers put up this advertisement at the trial site:
Become a volunteer in a trial for an HIV vaccine that works.

The researchers tell the community:

- They will only recruit trial participants from areas in the community that have the lowest rate of HIV infection, e.g. a convent for nuns. This is because a phase I preventative HIV vaccine trial is only for 'lower-risk' volunteers.
- Only trial site educators can run community education sessions about the vaccine and will also recruit trial participants.
- Only when a phase III trial eventually takes place will a Community Advisory Group (CAG) be appointed to advise and represent the community.
- Only people who have 12 years of formal education will be recruited to participate.
- Not everyone who is HIV negative will be accepted onto the trial. There are other selection criteria that will be used.
- Trial participants will be paid a lot of money and will be given other benefits if they participate.
- The scientific information about the test is too difficult to explain to the community, but the community should not worry because the Medicines Control Council (MCC) only gives permission for a trial if they believe the test vaccine is safe.

Community members tell researchers the following:

- Some of them have already received education from the **microbicides** research team who are doing research at the same site, so they do not need any further education.
- Someone tells a civic meeting that the selection criteria the researchers will use will discriminate against black people.

A newspaper report says the following:

Only trial participants who give up their right to privacy will be allowed to participate.

KEY WORD

Microbicides:
Vaginal products that can be used before sexual intercourse and which are being tested to see if they prevent the transmission of HIV and STIs. A successful microbicide has not yet been found, but there are several phase III clinical trials happening to test the efficacy of various microbicide designs. Microbicides are being tested in similar areas to those of HIV vaccine trials. For more information, visit the Global Campaign for Microbicides: www.global-campaign.org.



ROLE-PLAY 2 – PHASE III TRIAL

A research institution has identified a community in KwaZulu-Natal as a site for a phase III preventative HIV vaccine trial. An international company is sponsoring the trial and the trial is based on an HIV subtype not common to South Africa.

This community is in a semi-rural area where people are very poor and very few speak English. There is a high rate of HIV infection and few resources.

You need the following role-players:

- Researchers and research assistants (who can provide risk-reduction counselling for trial participants)
- A newspaper reporter
- Community members

The researchers and research assistants say the following:

- Getting informed consent from people in the community to participate in the trial should not be a problem because the literacy levels are high enough and the informed consent documents are in plain English.
- People who become infected with HIV during the trial because of their sexual behaviour will receive high quality care which will include ARVs if needed. But there will be no other lasting improvements in the health services for the community.
- They would welcome a Community Advisory Group (CAG) but the ethics committee dealing with their research application will see to the needs of the community.
- They want to include children under 18 years of age in the trial.

The newspaper reporter reports the following:

- Parts of the research protocol (plan) will not be made public, because the research design must be kept secret from competitors.
- Community members who participate in the trial must give up their right to confidentiality and details of their addresses. This is so that the media has access to them.
- HIV is widespread in this community.

Community members say the following:

Foreign sponsors are coming to infect the community with HIV through the trials.



ROLE-PLAY 3 – PHASE III TRIAL (which could be for a preventative and/or therapeutic HIV vaccine)

A research institution has identified a community of commercial sex workers in Cape Town as suitable for a phase III preventative HIV vaccine trial. The commercial sex workers are of all races and language groups. Their work is highly stigmatised and to a large extent they are still seen as criminals. A study shows that 29.2% of them are HIV positive. Many of them are under 16 years of age (and are thus still children) and have varying literacy levels. The Cape metropolitan area provides these sex workers with a range of health care, legal and other services. The organisation, ACSW (Activists for Commercial Sex Workers) also provides them with **advocacy**, education and advice services.

You need the following role-players:

- Researchers
- Police
- Commercial sex workers
- A lobby group that looks after the rights of commercial sex workers, like ACSW.

Researchers do and say the following:

- Together with the police they approach the commercial sex workers on the street to take blood samples.
- They also ask the sex workers to fill in a questionnaire about whether they are willing to participate in trials.
- They say that risk-reduction counselling during the trial is not important because the sex workers know what the risks are.
- They say that care and treatment, including ARVs, will be available for people who became HIV-infected during the trial. But there won't be any other lasting health services for trial participants.
- They say that getting informed consent from people to participate in the trial should not be a problem as most of the commercial sex workers can read.
- They say that only those sex workers who speak English or Afrikaans fluently will be recruited for the trial.

The lobby group says:

- *The trial should not be conducted with the commercial sex workers as they are a **vulnerable** group.*
- *Many are under the age of 16 years and this raises concerns about whether children could be included in this trial or not.*

KEY WORDS

Advocacy:

Promotion and support.

Vulnerable:

A group who are in danger or at risk.



Read through this activity and the role-plays, even if you do not have time to do the activity in your workshop. Each case study shows a different aspect of informed consent with a different group of people.

ACTIVITY 4: WHAT IS INFORMED CONSENT?

OUTCOMES OF THIS ACTIVITY

By the end of this activity, workshop participants should be able to:

- Explain what informed consent means.
- Apply the principles of informed consent in practical situations.

MATERIALS NEEDED

- See the checklist of resources needed on page 7 of Module 1.
- Copies of the *HIV Vaccines Learner's Handbook* or photocopies of pages 14–16 in Section 1.
- Photocopies of the case studies on pages 53–56 of this module.
- Use overheads on informed consent.

TIME: 40–60 minutes

PREPARATION

- Re-read Section 1 pages 14–16 and prepare your input on informed consent.
- Read through all the case studies (on pages 53–56) and the *Possible answers* that follow.
- Photocopy the case studies.
- Make photocopies of any handouts needed (see process notes).

PROCESS

1. Work in four small groups. Give each group one of the case studies to work on.
2. Ask each group to spend 20 minutes reading the case study and discussing the questions. They can record their answers on flipchart paper.
3. Work as a large group. Read each case study out loud. Then ask the group to report back their answers.
4. Finally, ask the plenary group how we can ensure that legal and valid consent is obtained in each situation. Possible answers are given on pages 57 to 58.
5. Sum up and fill in any gaps by using the relevant overheads.
6. Refer participants to the *HIV Vaccines Learner's Handbook*, or give them copies of pages 14–16 of Section 1 for work covered in this activity. They may also want copies of the case studies and the answers.



CASE STUDY 1: ADOLESCENTS AND INFORMED CONSENT

Researchers want to conduct a phase III preventative HIV vaccine trial among sexually active **adolescents** from the community.

Discuss these questions:

1. Can adolescents give legal consent to participate? Should researchers get valid consent on behalf of the adolescents from their parents/guardians? Explain your answer.
2. At what phase in an HIV vaccine trial should adolescents be included and why?
3. Parliament has asked you to recommend principles that should be included in the law to protect adolescents if they participate in preventative HIV vaccine (or similar) trials. What principles would you recommend?
4. What are the problems with recruiting adolescents onto the trial? What are the advantages?
5. Should adults of 18 years or older also be protected? Why?

KEY WORD

Adolescents:

As a general principle, UNICEF, UNAIDS and WHO define 'young people' as those aged 10–24 years, including adolescents (10–19) and youths (15–24).



CASE STUDY 2: PRISONERS AND INFORMED CONSENT

The University of Cape Town (UCT) wants to research a new HIV test to see if it is more reliable and affordable than existing HIV tests. The researchers want to conduct the research in a population that has already been tested for HIV, and where there is a large percentage of HIV positive people. They approach the local prison. The prison warden thinks it's a wonderful idea. She calls the prisoners together and encourages them to participate. She says that prisoners who participate will be given an opportunity to change their daily routine. Later, when prisoners visit the prison health care worker, they are given information about the research trial and are asked to give individual voluntary consent to participate.

Discuss these questions:

1. Can the prison warden give consent for the prisoners to participate in the trial? Give reasons for your answer.
2. Can individual prisoners give consent to participate in the trial?
3. Do you have any concerns about how valid this consent is?
4. Which other groups do you believe are especially vulnerable and may not be able to give informed consent, or may experience difficulties in giving 'free' informed consent?



**CASE STUDY 3: WOMEN AND INFORMED CONSENT
(This could be a preventative and/or a therapeutic HIV
vaccine trial)**

Thandi's husband, Malcolm, is a member of the civic organisation of Kayaletu. This organisation, together with other community organisations, has agreed that phase III HIV vaccine trials can take place in Kayaletu. Malcolm tells Thandi that she should participate in the trial because it is her duty to do so. She feels obliged to participate and gives her consent even though she does not really want to do so.

Vuyo, Rashida's husband, is an elder with some standing in the community. Although the community has agreed that phase III trials may take place, Vuyo is still not happy with it. He tells Rashida that she may not participate in the trial.

Discuss these questions:

1. If Malcolm informs the researchers that Thandi is participating in the trial, is this legal consent?
2. If Rashida gives informed consent even though her husband objects, is this legal informed consent?
3. In each case, what elements of informed consent are lacking or are relevant?



KEY WORD

Genetic testing:

This involves taking samples from body tissues, including blood, to examine genes or parts of genes for various reasons, e.g. to find out if a person is at risk of developing a particular disease. Genetic testing also includes biochemical tests for the presence or absence of key proteins that may explain how or why certain people develop a disease or how and why people respond to a disease in different ways.

In HIV vaccine research, genetic testing could be used to learn more about different kinds of immune responses to HIV, which could help with further development of a vaccine. Blood samples taken during clinical trials may be used for genetic testing. If so, there must be separate informed consent from the trial participant for these tests to be done on his or her blood samples.

CASE STUDY 4: A COMMERCIAL SEX WORKER AND INFORMED CONSENT

Violet is a commercial sex worker on Point Road in Durban. One day a researcher and a policewoman approach Violet. The researcher asks Violet if she may draw blood from her for a research project. Violet is given no further information about the research, except that it will involve the HIV in her blood if she is infected. Under the circumstances she feels she should give her consent for the blood to be drawn.

Discuss these questions:

1. Must the researcher get informed consent from Violet to draw her blood? If so, then what element/s of consent are lacking in the way the researcher went about getting her consent? What can Violet do about this?
2. How should the research institution get informed consent from Violet? What if they want to store Violet's blood sample and later use the blood to do other tests like **genetic testing**?



POSSIBLE ANSWERS OR INFORMATION RELEVANT TO THE CASE STUDIES

Case study 1: Adolescents and informed consent

Section 71 of the National Health Act (2003) allows for research or experimentation in children, under certain strict conditions. However, at the time of writing this Manual, these provisions are not yet in operation and regulations have not yet been finalised.

Adolescents and informed consent is a topic dealt with in the South African ethical and good clinical practice guidelines.

Case study 2: Prisoners and informed consent

Usually the person who is to participate in the clinical trial must give independent informed consent. Only individual prisoners themselves can give consent to participate in the trial – the prison warden cannot consent on their behalf.

Because of the power relationship between prisoners and their wardens, extra care should be taken to make sure that the consent is free and voluntary. Other specific communities may also be considered vulnerable because of factors like poverty, limited access to health care, etc. The Department of Health's *Ethics in Health Research: Principles, Structures and Processes (2004)* in 5.11 on page 27, discusses the ethics of research involving prisoners. *The Department's Guidelines for Good Health in the Conduct of Clinical Trials in Human Participants in South Africa, Clinical Trials Guidelines 2000* also addresses research involving prisoners and other special classes of participants e.g. people with mental disabilities or people from vulnerable communities.

Case study 3: Women and informed consent

A husband cannot give informed consent on behalf of his wife to participate in an HIV vaccine trial. So Thandi must give her own independent informed consent.

From a human rights and legal point of view, Rashida's independent informed consent is legal and valid. The views of her husband should not deny her the opportunity to participate. Her right to equality must be respected.

Remember that when it comes to informed consent, the law is interested in whether or not the person giving consent has the legal capacity to do so. This case example may bring out discussion about the nature of women's human rights, or about the place of cultural values and traditions in the Bill of Rights. The Constitution is clear that all rights, including cultural rights must be exercised in a manner that is consistent with the Bill of Rights.

For access to the *National Health Act*, visit www.info.gov.za/documents/index.htm.



Case study 4: A commercial sex worker and informed consent

Because of the power relationship between commercial sex workers and police, we can question whether Violet gave her consent freely and voluntarily to have her blood drawn.

The researcher should give full information about all the research to Violet. She should first allow Violet the opportunity to give informed consent before she asks permission to draw blood. Most importantly, she should not ask for informed consent in front of a policewoman. Violet also did not receive full information about the research. So taking the blood can be seen as an assault on Violet and she can lay a criminal charge.

From a human rights point of view, Violet should also be given the opportunity to find out her HIV status if tests are done on the blood sample. And she should also be offered pre- and post-test counselling. Violet also needs full information about the storage of the blood samples, how privacy will be maintained and whether the blood samples will be used for additional research.

Separate informed consent is necessary for genetic testing. Genetic testing raises further ethical and legal concerns, e.g. concerning privacy – ideally there should be laws regarding privacy of data resulting from genetic testing.

ACTIVITY 5: WHAT IS THE RIGHT TO PRIVACY AND CONFIDENTIALITY, AND WHAT IS UNFAIR DISCRIMINATION?

OUTCOMES OF THIS ACTIVITY

By the end of this activity, workshop participants should be able to:

- Explain HIV vaccine trial participants' right to confidentiality and right to equality, and why these are important.
- Discuss unfair discrimination experienced by HIV-positive people, why it occurs and what can be done to prevent or address it.

MATERIALS NEEDED

- See the checklist of resources needed on page 7 of Module 1.
- Copies of the *HIV Vaccines Learner's Handbook* or photocopies of pages 13–14 and 16–17 of Section 1.
- Photocopies of the McGeary case on page 60, if necessary.
- Use overheads on the right to privacy and confidentiality, the right to equality and non-discrimination, and why it is important to protect HIV vaccine trial participants.

TIME: 40 minutes

**PREPARATION**

- Read Section 1, pages 13–14; and pages 16–17 of this module.
- Write up the following questions on a flipchart for discussion or prepare an overhead of them.
- Make photocopies of any handouts needed (see process notes).

QUESTIONS FOR DISCUSSION

1. *What rights were violated in the McGeary case?*
2. *What action did McGeary take against the doctor?*
3. *Why is the McGeary case important to people who participate in HIV vaccine trials.*
4. *What do you think trial-related discrimination means? Can you think of some examples that could happen in preventative and therapeutic HIV vaccine trials?*
5. *Why is it important that we protect an HIV vaccine trial participant's right to privacy and confidentiality?*
6. *When do you think the right to privacy and confidentiality does not apply?*

PROCESS

1. If they have copies, ask workshop participants to turn to the information block called 'The Right to confidentiality' in the section on Human and legal rights in the *HIV Vaccines Learner's Handbook*, or hand out photocopies of the McGeary case.
2. Work as a large group. Read the McGeary case study on page 60 to the group.
3. Ask participants to work in pairs to discuss the questions on the flipchart/overhead.
4. When they have finished, they should report to the plenary session.
5. Refer to Section 1, page 17 for possible answers to the McGeary case. Refer to Section 1 pages 13–14 for possible answers about unfair discrimination. Speak about different strategies for addressing unfair discrimination, including lobbying politicians to break down stigma, and as a last resort, taking legal action.
6. Use the relevant overheads to sum up your key messages.
7. Refer participants to the *HIV Vaccines Learner's Handbook*, or give them copies of pages 13–14 and 16–17 of Section 1 for information covered in this activity.



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 compensation.

(Jansen van Vuuren versus Kruger, 1993)



ACTIVITY 6: HOW DOES THE DRAFT SAAVI PREVENTATIVE HIV VACCINE TRIAL PARTICIPANT CHARTER OF RIGHTS EXPLAIN THE HUMAN RIGHTS OF TRIAL PARTICIPANTS?

OUTCOMES OF THIS ACTIVITY

By the end of this activity, workshop participants should be able to:

- Explore the meaning of the basic elements of the draft *SAAVI Preventative HIV Vaccine Trial Participant Charter of Rights*.
- Assess whether the Charter adequately covers trial participants' rights and the human rights issues of trial participation.

MATERIALS NEEDED

- See the checklist of resources needed on page 7 of Module 1.
- Copies of the *HIV Vaccines Learner's Handbook* to work through. It includes the Charter.
- Use overheads on the right to privacy and confidentiality, the right to equality and non-discrimination, the right to human dignity, the right to have access to health care services, what is a charter, and the draft *SAAVI Preventative HIV Vaccine Trial Participant Charter of Rights*.
- Where necessary, make photocopies of the draft Charter (see Appendix 3 at the end of Section 1) and the task on page 63, for each of the groups.
- You need flipchart paper, kokis, pencil crayons, glue, scissors, and old magazines, for participants to make posters.

TIME: 2 hours

PREPARATION

- Use your overheads and prepare a presentation beforehand using the latest draft of the Charter. The current draft is included in Appendix 3 at the end of Section 1. Your presentation should cover the following topics and should remind participants how the provisions in the Charter reflect the various human rights in the Bill of Rights.
 - a) What is a Charter and why is it useful? (See the *Did you know* on page 19 of this module.)
 - b) Preamble
 - c) Informed consent
 - d) Non-discrimination and human dignity
 - e) The right of access to health care services
 - f) The right to privacy
 - g) Responsibilities of trial participants
- Photocopy handouts of the Charter for each participant if necessary, and photocopy the task on page 63 of this section for each of the groups.



PROCESS

1. Before presenting or showing the Charter, ask workshop participants what they know about Charters – what they are, what they try to do and why they are important. Then ask what they think should be included under each of the headings in a Charter. (There is a copy of the *Patients Rights Charter* in Appendix 2, Section 1 that you can show as an example of another health Charter.)
2. Give each workshop participant a copy of the draft *SAAVI Preventative HIV Vaccine Trial Participant Charter of Rights* or use the Charter in the *HIV Vaccines Learner's Handbook*.
3. Do a brief presentation on the Charter.
4. Work in six small groups. Give each group one of the following sections of the Charter and ask them to do the specified task:
 - Preamble
 - Informed consent
 - Non-discrimination and human dignity
 - The right to have access to health care services
 - Right to privacy
 - Responsibilities of trial participants
5. Ask participants to display their posters – in the order they appear in the Charter. Do a walk-about during which each group presents their poster and gives a summary of the questions discussed at the beginning of the task – follow the order of the sections in the Charter.
6. Conclude the session by summarising the main points given by participants about the Charter and its value. Fill in any gaps.
7. Refer participants to the *HIV Vaccines Learner's Handbook*, or give them copies of pages 19–21 and Appendix 3, from Section 1, for information covered in this activity.

SUM UP

Use the overheads to summarise this section of the workshop, as well as the points under, *To Sum Up*, on pages 21–22 of Section 1. If you do not have a copy of the *HIV Vaccines Learner's Handbook*, you can give copies of pages 21–22 to your workshop participants.

**Task**

1. Read through your section of the Charter and discuss these questions:
 - a) Do you agree with all the provisions in this section of the Charter? Which do you not agree with and why?
 - b) Are all these provisions practical and realistic? Why or why not?
 - c) Do you think the section favours the trial participants too much, or the researchers too much, or is there a good balance?
 - d) How can the section be used to promote people's human rights?
 - e) Which of these provisions apply to therapeutic HIV vaccine trial participants? What other provisions should be included for them?
2. Make a poster to educate your community about the main points in your section of the Charter. You can use words, pictures, drawings etc. to explain the following:
 - The most important and useful issues covered in the section.
 - How this section of the Charter will help someone know their rights and prepare them for participation in a trial.