

**BEST PRACTICES FOR SHORT-TERM HEALTHCARE MISSIONS**

Questions: What is the role of a procedural consent when we work in another culture?  
 What are the key points of cross-cultural procedural consents?

Participants in discussion	Background (perspective)
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Why is this important? This is an issue of trust and perceptions.	

**Biblical concepts involved**

Beneficence

[Luke 6:31](#)

Do to **others** as you would have them do to you.

[Titus 2:7](#)

In everything set them an example by doing **what is good**. In your teaching show integrity, seriousness

Do not harm

[Romans 13:10](#)

Love does no **harm** to its neighbor. Therefore love is the fulfillment of the law.

*Introduction*

When working in international settings, a healthcare mission team may wish to provide preventive, diagnostic or therapeutic medical/dental intervention to appropriate candidates. As Christian healthcare professionals we have the opportunity and responsibility to properly inform the patient/family/community and recommend a treatment in concert with God’s will in an effort to restore wholeness. These situations are inherently different than participatory education or community health surveys namely in that there is a risk of an adverse event or even death.

As Christian healthcare professionals we must avoid the temptation to think that all people think as we do and, therefore, eagerly accept the “blessings” medicine from the developed world – including the informed consent. The informed consent process may be inappropriate in some cultural settings. For

example, in the traditional Jewish Biblical legal system, the body is considered to be given by God to man as a trust to respect and preserve. Therefore, the individual has no absolute right to his/her body to make decisions as to medical treatment – unless there are two options that are equally good<sup>1</sup>. Thus the healthcare professional would make the decision in most cases.

*When should informed consent be obtained?*

The UNESCO Universal Declaration on Bioethics and Human Rights (October 19, 2005) Article 6.1 states:

*Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.*

Since individuals can perceive disease and treatment differently, we should not assume that all people will perceive a diagnostic or curative treatment as desired or beneficial. In loving relationships, people routinely obtain the consent of the other person, even if what is being offered is perceived as good. This happens around our dinner table most every night. In other words, I do not put a slice of chocolate cake on my daughter's or wife's plate without asking if they want it. If that is the case for something good, how much more should we do when we are offering something of benefit, but often cloaked in at least momentary discomfort. The person who asks for permission prior to doing something to another individual recognizes the dignity and autonomy of the other person. There is implied respect whenever a person is asked what they want. We don't want to be in the position of injuring a person against their will. God gave us the opportunity to choose and we must avoid coercion of others.

We think that the answer is: Christians should uphold the highest in interpersonal standards, and thus, should be asking people for their permission before performing all preventive, diagnostic and therapeutic medical interventions. This means that consent should be obtained in situations including drawing blood, providing vaccines or PPD testing or even performing a dental extraction.

*Who should consent?*

The consent process is largely predicated on the concept of a person making an autonomous decision to accept or reject a proposed course of therapy<sup>2</sup>. That is all persons who have achieved an age of majority and are mentally competent should be given the opportunity to consent or refuse services. We don't want to be in the position of injuring such a person against their will. God gave us the opportunity to choose and we must avoid coercion of others in turn. Those who have not achieved the age of majority and/or who are not mentally competent have decisions made for them by their nearest relative or guardian (cultural or legal). And even those who are the age of majority and mentally competent can choose to defer their prerogative (substituted judgment)

to elders, clinicians, relatives, or leaders. These principles should be able to work in any culture.

Implicit in the consent process is the assumption that the person understands what is being offered, the potential benefits and risks, and is able to communicate those wants to the person offering care. Going back again to the family dinner table, we would not ask our 18 month daughter whether she wanted something on her plate because she did not understand the benefits of what was being offered and was unable to communicate.

In cross-cultural settings, the partnership required such that a person understands what is being offered is often challenging. We must overcome language (body language, too), cultural viewpoints, limited knowledge of how curative medicine/dentistry works. Occasionally the intellect or mental status of the person consenting is not sufficient to reasonably make a decision. Once there is understanding of what is offered, we have a responsibility to make sure that the person has the capacity to weigh the options. Individuals who appear to be locked into a decision and will consider no other, may not be giving informed consent. Similarly those who cannot communicate their desires adequately cannot give informed consent.

The United States is unique, in part, because of its predominate focus on the individual. Individualistic assumptions underlying current bioethics guidelines may not be universally applicable in other cultures<sup>2</sup>. In the US, “substituted judgment” or paternalism is also practiced when a child has not reached the “age of majority” or when an individual patient is clearly incompetent to judge (e.g. critical illness or dementia). At that point we look to the closest relative.

In Europe there are differences in the approach to bioethics. In southern Europe the person is thought to have a positive duty to maximize his/her own health and to follow the doctor’s instructions. Conversely, some Europeans retain the negative right to override the doctor’s decision<sup>3</sup>. In other areas of the world, paternalism, where the healthcare professional assumes the role of consenting party, is still alive.

Other societies are likely to be more family or community focused. This means that the consent process may involve other people in addition to the patient. In some cultures family leaders or even community leaders must be consented. When obtaining a consent from a patient from a community-focused society, the consent process may hinge upon having certain individuals present. Therefore, factoring in more time to obtain a consent may be necessary.

Many people feel uncomfortable with the concept of making a medical choice, especially one that contradicts what the healthcare professional has recommended. Many people will ask the healthcare professional to decide, stating “you know best”, or “we trust you” or “we trust that God has given you the skills and understanding to make this choice”.

At its most basic, the informed consent may represent a means by which healthcare professionals can say, “This is what we are planning to do, is this OK with you?” Thus the informed consent may be seen as a reminder to the patient/family that something involving risk is being performed.

It is important to note that there are a number of differences in societies. Yet, not all individuals within a society have a single set of guiding values or allegiances, thus they may respond in ways atypical to what is common within their society.

#### *The consent from a Kingdom perspective*

If taken from a Kingdom perspective, the consent should be an opportunity to build a loving relationship between God, the patient and the healthcare professional. To that end, God should be involved each step of the consent process. If we were to engage in Kingdom thinking the consent process could look something like this:

1. Seek God's discernment and wisdom (possibly before interacting with the patient)
2. Inform
3. Suggest a potential treatment including alternatives, risks, and benefits
4. Pray
5. Request permission
6. Pray

#### *Challenges of obtaining a consent in a cross-cultural setting*

The cross-cultural nature of the healthcare provider-patient relationship during a short-term healthcare mission trip makes the consent process difficult. Essentially, a consent reflects the creation of a partnership between the healthcare professional and the person who needs care. The contractual process can be very different depending on the norms of the cultures. Some cultures are very familiar with the concept of paper contracts while others are not. In some cultures it may not be practical to obtain a paper-based informed consent. There are a number of other issues regarding time, literacy, relationships, family and community which can affect the informed consent process.

#### *The consent document is not a guarantee*

Since the informed consent appears to be a contract, some individuals may assume that they are entitled to a perfect outcome. It is important that people understand that as a healthcare professional, that one is not making any guarantee regarding the procedure. Conversely, the concept of "doing one's best in an effort to help the patient" should be put forth. Sometimes a story with drawings/picture can be helpful to illustrate the concept of risk. For example:

##### **The farmer**

*This is like a story that Jesus told. A farmer goes out to the field to plant seeds. Some of the seeds fall on the rocky path, some grow well but are destroyed by weeds and some grow and produce a crop. In this story, I am like the farmer and you are like the seed. As a healthcare professional, my goal is to be used by God to help restore you to health. Most of the time, everything that I do works well – the seeds produce a crop. A small part of the time there are problems during the procedure – the seeds that are on the rocky path. A small part of the time there are problems after the*

*procedure – the seed that gets choked by the weeds. By trying to do everything right our team increases the chances of your recovery. Do you understand?*

### *Time and trust issues*

Issues of trust and mistrust are critical in the consent process<sup>4</sup>. The time commitment for a short-term healthcare mission team is usually less than 3 weeks. The short duration of the commitment can make trust more difficult. Given a similar situation in our own lives, it would be more difficult to consent to a procedure/surgery if the surgeon was leaving in a few days and would never return. Follow-up by an indigenous healthcare partner and a process by which post-procedural problems are handled may be critical in assuaging concerns.

### *Education is needed to properly obtain an informed consent*

The consent process by necessity requires an educational effort on the part of the healthcare professional. A study of German and Turkish women in Germany showed that understanding of female body functions was low in the German (13% of German women had a very good understanding) and even lower in the Turkish group<sup>5</sup>. Thus, we should not assume that all people have a correct understanding about the how organs relate to body function. Therefore, any description of a procedure should explain what is wrong and how that affects the normal functioning of the organ. For example:

*“You have a large ball of worms in your stomach. The stomach helps to digest food which gives you energy. If your stomach is not working right due to the worms, your body will become thin and you will get sick. Removing the worms by making a cut here (show location and size) and taking out the worms will allow your stomach to be well. After we repair the cut, you can be healthy again.”*

A study performed by Coombe et al found that people in a developed Western country often did not understand risk, benefits and complications associated with lower endoscopy<sup>6</sup>. When working in a cross cultural setting, the potential for confusion about what procedure/surgery is being offered, and the potential risks and benefits, is heightened. Education about a procedure/surgery may be enhanced by using pictures/drawings, anatomically correct dolls, skits, indicating where the surgery will be performed on the patient’s body, etc.

### *Task versus relational cultures*

Some societies tend to be task oriented while others tend to be relationship oriented. For example, in the United States, obtaining a consent is handled in a brief encounter solely focused on the procedure/surgery as a means to benefit the patient. In other cultures, the building of trust and relationships, sometimes with “tea time” is essential before the procedure/surgery can proceed. Therefore, a consent process that normally could take 5-10 minutes in a Westernized culture, may take hours in another.

*Is the consent a broad time-independent process?*

The consent process often allows the healthcare professional to set into motion a sequence of tests or therapies. While this approach is broadly understood in Western developed countries, people from other cultures may not understand that they have given consent for *today's* procedure. Therefore, it may be appropriate to obtain at least verbal consent whenever the patient presents for more therapy (i.e. dialysis or chemotherapy)<sup>2</sup>.

#### *The role of local partners or healthcare professionals*

Given the cultural differences, it may be more appropriate to have a local healthcare professional or partner obtain the consent or guide one through a typical consent process. Given that the process of consent may vary between cultures it is important that the key pieces of the consent be preserved including the principles of “patient autonomy” and “substituted judgment”. This may be a great opportunity for healthcare professionals from different cultures to talk about what is important – in the light of what God would want.

Yet, this process can be frustrating and can, if not handled well, lead to a loss of love between mission partners. Short term mission teams who are unwilling to contextualize their consent process may want to re-consider whether God is really calling them to work in a cross-cultural setting or whether real changes are required. Similarly, mission partners who are rigid in their approach to the consent process may confront the same choices. There is a great need for flexibility in methods used during the informed consent process<sup>7</sup>.

#### *We should not withhold information*

In most cultures there are healthcare professionals who elect to withhold information regarding a patient's condition, planned treatment or even expected outcomes. In a study by Yousef et al published in 2007, a questionnaire-based cross sectional survey among doctors in the two tertiary care hospitals, one in Malaysia and the other in Kashmir, was performed.

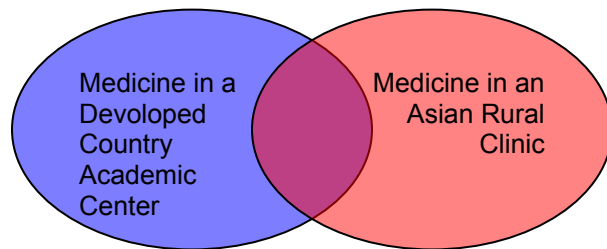
*Awareness on informed consent was universal. As compared to doctors in Malaysia, doctors from Kashmir showed a tendency to reservedly disclose medical information (p-value equals 0.051) and withhold it, if it was deemed potentially harmful (p-value is less than 0.001) or requested so by relatives (p-value is less than 0.023). They also withheld some information from female patients (p-value is less than 0.001). When consent was refused despite needing lifesaving intervention, the majority of both respondents (73 percent versus 80 percent) considered intervention without consent to be justified. Respondents from Malaysia felt that parents could refuse treatment on their children's behalf on the basis of their beliefs (p-value is less than 0.001).*

As followers of Christ, we should attempt to withhold the truth about a situation. Yet, it is important to remember that in some cultures (or with some individuals) more information is not necessarily better. Deception or coercion, even when used to achieve a “good” outcome, are inconsistent with a Kingdom-focused approach. Hence, the argument for primacy of patient autonomy, tempered by substituted judgment when appropriate.

*Consents obtained in the middle ground between cultures*

Physicians and dentists frequently presume that they can deliver the same care in the country that they are visiting that they provide at home. This perception is often incorrect. There is an intersection between the two medical environments. In this intersection, the medicine/dentistry provided may not be entirely like that in either environment. Electricity may be off for a part of the day, the operating room may be cold or not very clean, anesthesia may be very different and the time needed to teach (with translation) while performing the procedure/surgery can make the procedure longer than normal. Furthermore, a study has shown that when a new procedure/surgery is introduced in an area/clinical unit, that there is an initial period of greater hazard/risk higher to the patient<sup>8</sup>.

Imagine the challenges when a short-term specialty surgical team from Singapore teams-up with a group of Chinese physicians to perform orthopedic surgery for disabled children in a community hospital in a small town:



Therefore, adapting the surgical approach so that one tries to do less invasive or risky types of surgery and fewer cases than what is done at home is most appropriate. If this approach is adopted, it will impact the consent process.

*Emergency consent*

Occasionally there are emergencies that require an immediate response. The major goal of the emergency consent should be that of protection of the patient and oversight for the healthcare professional. In these situations, a verbal description of the problem and what is planned to resolve the problem can be offered to the patient/family.

*Situations where a patient or family is unable to consent*

In the event that nobody is available to represent the patient, an effort should be made to obtain the agreement of another healthcare professional prior to proceeding. This provides the opportunity for another point of view, which could lead to a different therapeutic approach.

Basic ethical principles are the hallmark of all consent processes

The consent process is built on respect for individuals, their communities and their cultures.

The four clusters of principles are respect for autonomy, nonmaleficence, beneficence and justice. Autonomy (derived from the Greek *autos* 'self' and *nomos* 'rule') relates to the freedom of people to make intentional decisions independent from controlling influences. Nonmaleficence is the obligation to do no harm, whereas beneficence relates to helping others and promoting good. Justice is the impartial, equitable and appropriate treatment of all – the fair distribution of benefits, risks and costs.<sup>9</sup>

### *Autonomy*

Individuals and their communities have the right to make decisions contrary to what we as healthcare professionals recommend. This position is accepted in virtually all cultures<sup>10</sup>. However, there are differences even in European countries regarding the extent to which the autonomy of surgical patients is supported by nursing staff<sup>11</sup>.

### *Substituted judgement*

There are situations where a person's ability to make decisions on their behalf is limited due to minority age, mental or psychiatric diseases. Protocols for assessing competency are available<sup>12</sup>. In some cultures we are compelled to accept the voice of another on the patient's behalf. The head of the family or a community leader may make the decision, if this is culturally appropriate, to consent to a procedure/surgery. In Saudi Arabia, a guardian could be appointed by the Qhadi (magistrate), to give consent to the necessary management for minors<sup>10</sup>.

### *Nonmaleficence*

As healthcare professionals, we have the responsibility to do no harm. We should never allow our selves to be placed in a position where we would only add to the pain and suffering of a person – while offering no potential for a restoration of health. Nurses are often the first to point-out hopeless situations in which no potential benefit can occur with more therapy.

### *Beneficence*

We should always strive for wholistic restoration of a person based on the work that God directs us to do. We should do what is best for the patient. As Christians we should strive for physical, emotional and spiritual restoration as a result of our God-directed work. Healthcare professionals should make sure that what they are recommending is in concordance with their own knowledge of the procedure. We should give careful consideration to recommending a treatment to which we would be unwilling to subject our own family.

### *Justice*

As healthcare professionals we should do all that we can to impartially select patients for curative care regardless of their physical, mental or spiritual attributes or ability to compensate us for our work.

## Sender Perspective

### *Before*

Many churches and individuals have received requests for specialized therapeutic medical/dental intervention from individuals and missionaries around the world. Most of the time these requests are passed along to the short-term healthcare missions team. We speculate that senders probably spend virtually no time considering whether or not the short term healthcare missions team will obtain informed consents.

### *During*

If a short-term healthcare missions team is providing specialized therapeutic medical/dental intervention, senders may be very interested in receiving updates from the team. Oftentimes, a surgical intervention is covered with prayers – both for the patient and for the surgical team. Knowing the surgical outcome in a prompt timeframe is very helpful.

### *After*

The major issue is whether the church/sending organization bears responsibility should the patient die or experience significant adverse effects. Should the specialized therapeutic medical/dental intervention successful, then the glory goes to God. Should a team be found to have performed medical/surgical interventions without the permission, there could be negative backlash.

## Goer Perspective

### *Before*

Occasionally team members receive a plea (often by e-mail) for help for a person with a serious disease. Beyond praying for a person, it may seem reasonable to use all of the resources that God provides including recruitment of a surgeon or surgical team/dental or dental team.

Situations where only a limited number of surgical cases can be performed for a large population of needy people creates a rationing situation. This places the Christian healthcare professional in a very difficult situation. The criteria for receiving treatment should be stated in advance.

Success can create a problem similar to that encountered by Jesus – word of a cure spreads rapidly. It would be important to think about one's strategy beforehand. Is this a one-time only offering?

Preparing people for both success and failure is critical. If a surgical treatment works, will everyone give the credit to God? What other conclusions can people draw? They may be grateful to “the god of technology”, “the Western medicine god”, etc. – and in terms of God's Kingdom we may be worse off than when we started.

Short-term healthcare mission teams should never be seen as a means by which care can be provided without all of the “hassles” of the developed world

including informed consents and documentation. Nurses should also seek permission before performing any invasive care.

### *During*

Obtaining the informed consent it is important to make sure that there is no coercion or unrealistic expectations for the patient. There are often (limited) time issues which can make it seem appropriate to not spend the additional needed time to obtain the consent. For example should a signed consent be obtained prior to handing out medications? Before administering a PPD test? Giving vaccines? Novel means of documenting consent may be appropriate when large groups of people are being treated, i.e. video documentation of verbal consents.

How we conduct ourselves speaks volumes of who we serve – God. The informed consent can be seen as a sign of respect which enhances the relationship between healer and the one who needing healing. The consent process should be covered in prayer.

Should there be an adverse event related to an intervention and no consent has been obtained, the short-term healthcare team would be liable. In this situation, the team could expect anger and hostility from the family and/or community.

There are number of cross-cultural situations where one's motives can be misunderstood by other healthcare professionals. It will also be necessary to contextualize the use of a specialized therapeutic medical/dental intervention to other healthcare professionals who might think that other motivators (greed, enhancement of position, simple curiosity) may be operative.

### *After*

Obviously one can bask in the satisfaction of knowing that a person was helped by God through the use of a specialized therapeutic medical/dental intervention. However, should a poor outcome occur, the team leader/ team member is likely to have problems with the recipients, partners and senders.

## **Recipient Perspective**

### *Before*

The motivation for people in need of healing, but have failed traditional therapy, is largely that of desiring to be healed/restored to health. Like other people, there may be unrealistic expectations of the effect of the specialized therapeutic medical/dental intervention and even an unconscious de-linking of the medication and God's provision.

### *During*

The patient can have a variety of different outcomes – completely healed, healed but with adverse effects of the specialized therapeutic medical/dental intervention, much improved, or worse/dead.

### *After*

If the specialized therapeutic medical/dental intervention is successful, there may be a great deal of gratitude to God and to the people who were responsible for bringing the medication. If the specialized therapeutic medical/dental intervention does not have the intended consequence, it will be important to make sure that the team leader/team member and/or church provides for the consequences. People may be angry, hostile, sad or frustrated.

## Consensus Statement

There is full concurrence with Universal Declaration on Bioethics and Human Rights (October 19,2005) Article 6.1. Specifically, it is best to obtain permission/consent before any planned preventive, diagnostic or therapeutic medical/dental intervention. The consent process should be derived from a Kingdom viewpoint. This partnership between the helper and the person who is being helped demonstrates the goodness and restorative power of our Father in heaven.

1. As a healthcare professional pray and seek God's wisdom, discernment and permission prior to any consent.
2. Written consents are probably better, however, especially in a low literacy culture contextualizing the consent to a verbal agreement may be appropriate.
3. The consent should be in the language of the person who is undergoing the procedure with the language of the healthcare professional performing the procedure.
4. The name of the healthcare professional performing a procedure.
5. The organization to which the surgeon or one performing a procedure belongs.
  - a. This can be difficult to be determine. Given a healthcare mission, is the surgery or procedure being performed under the direction of the partner? Local healthcare professional team or institution? The sending organization? Leadership that with the mission team (if they are under a different name)? The best option, if possible, is that of the local healthcare professional team or institution or one's malpractice insurance carrier (home healthcare institution).
6. Provide basic information about the problem
7. Provide education as to what the body organ normally does
8. Know what is being done – in layman's terms
9. Review the risks
  - a. Make sure that the patient is familiar with the concept of risk/chance
    - i. Story of the farmer
  - b. Be told the risks as truthfully as is possible
    - i. No guarantees
10. Have a understanding of alternative treatment/diagnostic options
11. Pray
12. Receive a recommendation from the medical team which providing care for him/her
13. Understand that she/he has the right to refuse
  - i. If the procedure is refused, care will still be provided.
14. Provide a signature or mark or verbal agreement indicating their agreement.
15. Pray

A sample BEST PRACTICES short-term missions informed consent form is shown on the next page

[Translated with the languages of the patient and healthcare professional]

Informed consent

Date:

Time:

<input type="checkbox"/> I have sought God's Wisdom and Discernment prior to talking with the patient		
Patient name:		
Date of birth:	Age:	Gender:
Your Doctor/Dentist/Nurse:		
Your Doctor/Dentist/Nurse works for:		
Your problem:		
How does this differ from normal?		
How we plan to fix it:		
Here are the risks:		
This may be another possible way to heal your body:		
Prayer		
Recommendation:		
Is this plan OK?		
Yes	No	
Signature/mark of patient		
Signature/mark of other authorized representative:		
Your Doctor/Dentist/Nurse's signature:		
Prayer		

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## Appendix 1

### **UNESCO: Universal Declaration on Bioethics and Human Rights**

19 October 2005

#### **Article 1 – Scope**

1. This Declaration addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions.

2. This Declaration is addressed to States. As appropriate and relevant, it also provides guidance to decisions or practices of individuals, groups, communities, institutions and corporations, public and private.

#### **Article 2 – Aims**

The aims of this Declaration are:

(a) to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics;

(b) to guide the actions of individuals, groups, communities, institutions and corporations, public and private;

(c) to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law;

(d) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, while stressing the need for such research and developments to occur within the framework of ethical principles set out in this Declaration and to respect human dignity, human rights and fundamental freedoms;

(e) to foster multidisciplinary and pluralistic dialogue about bioethical issues between all stakeholders and within society as a whole;

(f) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;

(g) to safeguard and promote the interests of the present and future generations;

(h) to underline the importance of biodiversity and its conservation as a common concern of humankind.

## **Principles**

Within the scope of this Declaration, in decisions or practices taken or carried out by those to whom it is addressed, the following principles are to be respected.

### **Article 3 – Human dignity and human rights**

1. Human dignity, human rights and fundamental freedoms are to be fully respected.
2. The interests and welfare of the individual should have priority over the sole interest of science or society.

### **Article 4 – Benefit and harm**

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

### **Article 5 – Autonomy and individual responsibility**

The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.

### **Article 6 – Consent**

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.
2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made

only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.

3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

### **Article 7 – Persons without the capacity to consent**

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:

(a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent;

(b) research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and, if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights. Refusal of such persons to take part in research should be respected.

### **Article 8 – Respect for human vulnerability and personal integrity**

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

### **Article 9 – Privacy and confidentiality**

The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with

international law, in particular international human rights law.

### **Article 10 – Equality, justice and equity**

The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.

### **Article 11 – Non-discrimination and non-stigmatization**

No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.

### **Article 12 – Respect for cultural diversity and pluralism**

The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.

### **Article 13 – Solidarity and cooperation**

Solidarity among human beings and international cooperation towards that end are to be encouraged.

### **Article 14 – Social responsibility and health**

1. The promotion of health and social development for their people is a central purpose of governments that all sectors of society share.

2. Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, progress in science and technology should advance:

(a) access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good;

(b) access to adequate nutrition and water;

(c) improvement of living conditions and the environment;

(d) elimination of the marginalization and the exclusion of persons on the basis of any grounds;

(e) reduction of poverty and illiteracy.

### **Article 15 – Sharing of benefits**

1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:

(a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;

(b) access to quality health care;

(c) provision of new diagnostic and therapeutic modalities or products stemming from research;

(d) support for health services;

(e) access to scientific and technological knowledge;

(f) capacity-building facilities for research purposes;

(g) other forms of benefit consistent with the principles set out in this Declaration.

2. Benefits should not constitute improper inducements to participate in research.

### **Article 16 – Protecting future generations**

The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.

### **Article 17 – Protection of the environment, the biosphere and biodiversity**

Due regard is to be given to the interconnection between human beings and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity.

### **Application of the principles**

### **Article 18 – Decision-making and addressing bioethical issues**

1. Professionalism, honesty, integrity and transparency in decision-making should be promoted, in particular declarations of all conflicts of interest and appropriate sharing of knowledge. Every endeavour should be made to use the best available scientific knowledge and methodology in addressing and periodically reviewing bioethical issues.

2. Persons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis.

3. Opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted.

### **Article 19 – Ethics committees**

Independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level in order to:

(a) assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;

(b) provide advice on ethical problems in clinical settings;

(c) assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration;

(d) foster debate, education and public awareness of, and engagement in, bioethics.

### **Article 20 – Risk assessment and management**

Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.

### **Article 21 – Transnational practices**

1. States, public and private institutions, and professionals associated with transnational activities should endeavour to ensure that any activity within the scope of this Declaration, undertaken, funded or otherwise pursued in whole or in part in different States, is consistent with the principles set out in this Declaration.

2. When research is undertaken or otherwise pursued in one or more States (the host State(s)) and funded by a source in another State, such research should be the object of an appropriate level of ethical review in

the host State(s) and the State in which the funder is located. This review should be based on ethical and legal standards that are consistent with the principles set out in this Declaration.

3. Transnational health research should be responsive to the needs of host countries, and the importance of research contributing to the alleviation of urgent global health problems should be recognized.

4. When negotiating a research agreement, terms for collaboration and agreement on the benefits of research should be established with equal participation by those party to the negotiation.

5. States should take appropriate measures, both at the national and international levels, to combat bioterrorism and illicit traffic in organs, tissues, samples, genetic resources and genetic-related materials.

### **Promotion of the Declaration**

#### **Article 22 – Role of States**

1. States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration in accordance with international human rights law. Such measures should be supported by action in the spheres of education, training and public information.

2. States should encourage the establishment of independent, multidisciplinary and pluralist ethics committees, as set out in Article 19.

#### **Article 23 – Bioethics education, training and information**

1. In order to promote the principles set out in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments, in particular for young people, States should endeavour to foster bioethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about bioethics.

2. States should encourage the participation of international and regional intergovernmental organizations and international, regional and national non governmental organizations in this endeavour.

#### **Article 24 – International cooperation**

1. States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological

knowledge.

2. Within the framework of international cooperation, States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.

3. States should respect and promote solidarity between and among States, as well as individuals, families, groups and communities, with special regard for those rendered vulnerable by disease or disability or other personal, societal or environmental conditions and those with the most limited resources.

#### **Article 25 – Follow-up action by UNESCO**

1. UNESCO shall promote and disseminate the principles set out in this Declaration. In doing so, UNESCO should seek the help and assistance of the Intergovernmental Bioethics Committee (IGBC) and the International Bioethics Committee (IBC).

2. UNESCO shall reaffirm its commitment to dealing with bioethics and to promoting collaboration between IGBC and IBC.

#### **Final provisions**

#### **Article 26 – Interrelation and complementarity of the principles**

This Declaration is to be understood as a whole and the principles are to be understood as complementary and interrelated. Each principle is to be considered in the context of the other principles, as appropriate and relevant in the circumstances.

#### **Article 27 – Limitations on the application of the principles**

If the application of the principles of this Declaration is to be limited, it should be by law, including laws in the interests of public safety, for the investigation, detection and prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others. Any such law needs to be consistent with international human rights law.

#### **Article 28 – Denial of acts contrary to human rights, fundamental freedoms and human dignity**

Nothing in this Declaration may be interpreted as implying for any State,

group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity.